FEDERAL TRADE COMMISSION

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In the Public Hearing on:)
COMPETITION AND INTELLECTUAL)
PROPERTY LAW AND POLICY IN)
THE KNOWLEDGE-BASED ECONOMY.)
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Federal Trade Commission
Room 432
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The above-entitled matter came on for hearing, pursuant to notice, at 9:37 a.m.

P R O C E E D I N G S

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MR. COHEN: Good morning. My name is Bill Cohen. I'm an Assistant General Counsel here at the Federal Trade Commission, and I want to welcome you to our session this morning on Patent Law for Antitrust Lawyers.

We're now one day into our hearings and some may feel we are already in quite a swirl. In just our opening session we heard about concepts such as nonobviousness, disclosure requirements, reexamination procedures, prior art, and the nature of patentable subject matter.

And we heard that many of these concepts, or at least the effects of their application, may have increasing bearing in some antitrust contexts.

We thought that it might make sense to begin our inquiries here with a foundational day, something that will help familiarize ourselves with the language and the key concepts of the sister discipline that's becoming so much a part of our antitrust world.

We haven't designed this with a thought that any of you are going to go out after this session all ready to practice patent law. In fact, we have intentionally left out some of the elements that you would probably find in a standard nutshell treatment.

Instead, what we have tried to do is to design something that will help antitrust lawyers at the places where their practice intersects with intellectual property concepts.

And, more specifically, we have tried to make sure that we are presenting the basics that will help us deal with a complicated set of issues that we are going to face throughout the rest of these hearings.

We have multiple sets of participants here today. I may later be joined by Susan DeSanti from the FTC. She is Deputy General Counsel for Policy Studies.

I'm an antitrust lawyer. Susan is also an antitrust lawyer. We're not the ones you're going to be wanting to hear from this morning. We are here merely to ask questions and we think they will help us out with the real stars of our show who will be able to present what we think the antitrust lawyers need to hear.

We're lucky right now to have two of those three stars. Scott is here, too. Sitting directly to my right is Jay Thomas. Then we have Professor Lawrence Sung, and we also have Scott Chambers. I'll introduce them all more formally one at a time.

But before I go on to begin with a more complete introduction of Jay Thomas, I think I'll turn the podium over just for a little while to one more participant,

Bill Stallings, who is joining us from the Department of Justice, who will welcome you on behalf of the Antitrust Division.

MR. STALLINGS: Thanks, Bill. On behalf of the Department of Justice we want to thank everyone for coming here and also thank the FTC for organizing this event.

We are looking forward to the many informative sessions, and we particularly want to put a plug in for the sessions we will be hosting later in the spring where we will be discussing licensing issues, such as refusals to deal, the effects of particular types of licensing practices, standard-setting, patent pools and comparative international issues.

A lot of information can be found, of course, on our website and with that, that's all I need to say but thank you again for attending. And we look forward to seeing you in the future.

MR. COHEN: I'll note before introducing Professor Thomas we have had one last-minute substitution. Sitting next to me will be Suzanne Michel from the Federal Trade Commission.

Our first lecturer this morning is Jay Thomas who holds the position of Associate Professor of Law at George Washington University. He also serves as visiting

researcher in entrepreneurship and economic growth at the Congressional Research Service and instructor at the United States Patent and Trademark Office, Patent Academy.

He has previously served as a visiting fellow at the Max Planck Institute for Comparative and International Patent, Trademark and Copyright Law in Germany and visiting professor at the Institute of Intellectual Property in Japan.

Professor Thomas is the author of numerous articles on intellectual property law and also authored a patent law casebook and intellectual property treatise. I'll turn it over to Professor Thomas to begin.

PROF. THOMAS: Well, thank you very much for having me here this morning and I would just note how delighted I am to be part of such a distinguished panel of patent experts.

Lawrence, Scott and Suzanne and I all clerked at about the same time on the Federal Circuit. It's delightful to see just how well they have done with the years that have passed, so many of them, it seems, in such a quick amount of time.

But it's my job to be your headliner. I'm going to sort of start by going through some of the basics of how the patent system works and then I want to talk a

little bit about some of the policies that animate the patent system and some of the criticisms that it has encountered.

And then I'm going to weigh in a little bit more deeply with some of the patentability criteria, what one has to do, substantively, to have an invention be patentable. So let me weigh in without further comment.

Well, the first thing I'm going to talk about is sources of law. Where would you go if you wanted to look to see where the patent law was? Where would you find it? Well, one of the first places you look is the Constitution.

And, in fact, it is a granted right to Congress to enact a patent system. And that's set out in Article One of the Constitution. It's actually the only place in the original Constitution, setting aside the Bill of Rights, where you will find the word "right." And what it says is that Congress may give to inventors an exclusive right in their discoveries.

Now, Congress is permissibly given that ability. It doesn't have to pass a patent act, although the U.S. has since engaged in international treaties which oblige the U.S. to have a patent system. But again, the Constitution is just permissive. Congress may pass the statute. It doesn't have to.

The Congress did very early on. There's a 1790 Patent Act which is remarkably similar to what we're doing today. And actually you'll find that patent law is a venerable discipline that has a lot of ancient antecedents. And the statute has been augmented by a lot of judicial gloss.

Now, the current patent statutes, the Patent Act of 1952, occurs in Title 35 of the U.S. Code. I'm not sure we have advanced but perhaps we're not any worse. So that's the basic provisions we'll be talking in Title 35.

Now, as well, the Patent Office, and there is such a thing as a Patent Office. It's called the Patent and Trademark Office formally -- although sometimes I'll just call it Patent Office because it's a little less awkward -- has also set out a load of regulations. And you'll find those in Title 37 of the Code of Federal Regulations.

And finally, the Patent Office has also put out a book of its own practices. And it's called A Manual of Patent Examining Procedure. And they are two enormous tomes. You would not believe the girth of these weighty volumes. And these describe the internal practices of the Patent and Trademark Office.

They are not binding, it turns out, not even upon

examiners for the most part but what they do is again set out the way that the Patent Office tells the world it conducts business.

Now, it should also be noted that there is a specialized court in this area. There is something called the Court of Appeals for the Federal Circuit.

And it hears all appeals from, first, disgruntled applicants from the Patent Office, from applicants who have sought patent protection and been denied. It hears all those appeals but it also hears appeals in patent enforcement cases, patent litigation.

Now, there also has to be the case law of the Federal Circuit. And that's very important in this field. There's a specialized court and they speak to patent matters exclusively. So you're not going to get patent precedent any more from the regional courts of appeals, say the D.C. Circuit or the First Circuit. It all goes up to the Federal Circuit as a practical matter.

Now that I've given you some of the sources of law, I just want to give you the ten-cent tour of how the patent system works so it provides a framework for later discussion.

One of the first things to note is that patent rights do not arise automatically. They have to be affirmatively sought. That's very different from most

other intellectual property rights. Trademarks arise through use in commerce. There is a Patent and Trademark Office but it's just really a registration system for rights that already exist.

Same thing for the copyright office. Copyright arises automatically when I write something down and put it into tangible form. There is a copyright office but it just registers the rights and provides certain procedural advantages to copyright registrants.

And that's very different from the patent law. In the patent system inventors must draft applications that completely disclose and distinctly claim the invention for which a patent is sought.

And at that time it is presented to the Patent and Trademark Office and quasi-judicial officials called examiners review these applications. First they review the applications to make sure that they fulfill this disclosure requirement, that they completely disclose the invention such that a skilled artisan can practice that invention without undue experimentation.

Also, the application has to distinctly claim the invention. It has got to set out the technological territory. It's got to set out the deed, the lines of property that the applicant claims to be her own.

Now, it also has various substantive

requirements. It's got to be new. It's got to be nonobvious. It's got to be useful. It's got to fall within the statutory subject matter.

And we'll go through all those substantive requirements with my presentation and move into the others with my colleagues on the panel.

What do you get for your trouble? If you go through all this effort what is your reward? Well, issued patents ordinarily enjoy a term of 20 years, measured from the date the application is filed.

Now, note, there is no substantive right granted, generally speaking, until the patent is actually granted. So until you actually get the right you don't have any authority to enforce your patent. So, in effect, every day in the Patent Office in procurement is a wasted day. It takes a day off the term. But once the patent is granted you get the term based upon the date of filing.

And what are the rights that you receive? Patent proprietors obtain the right to exclude. It's important to note that the Patent and Trademark Office is not the FDA. It does not dole out marketing approvals. What you get essentially is a ticket to court. You get a right to exclude others from making, using, selling offering to sell or importing into the United States the patented invention.

In a sense, when a patent issues, all of us have the duty to avoid practicing that proprietary -- what's been appropriated through the patent.

The Patent and Trademark Office is not engaged in the patent enforcement business. It is up to the patent proprietor to enforce the right. It is her responsibility to monitor her competitors, determine whether infringement exists, and at that point to commence litigation. Litigation is wholly in the federal courts and suit may be brought the date the patent issues.

The scope of patent protection is founded upon but not limited to the claims of the patent. You recall that I said that patents have to be -- there has to be a distinct set of claims setting up the technological territory.

Protection is founded upon those words but it's not always limited to it. You get a little bit of play in the joints. There's a little wiggle room and it's called the doctrine of equivalents.

If I say I have a chemical process that operates at approximately a pH of 7.0, well, maybe the court will give me 7.5. Maybe it's approximately 7; they'll give me a little bit more perhaps. Actually, the doctrine of equivalents is in a bit of state of decline right now.

But that will be revealed by my colleagues.

The patent is presumed to be valid. I should say not invalid is the usual phraseology in patent speak. But the accused infringer will usually assert, well, I'm not doing it. I don't infringe.

They will also assert that the patent was improperly granted, that even though the Patent and Trademark office approved the application that this step was improper because it didn't meet the requirements of the Act.

Perhaps, for example, there's public domain information that the Patent Office didn't know about and so this additional information is brought by the accused infringer to the court which then assesses anew. But, again, that burden of production and persuasion will lie upon the accused infringer.

Now, why do we have a patent system? Well, let me say a lot of these justifications have sort of come around late. The Framers didn't really know much in the way of economics or technological progress. They knew a little but they were pretty much following antecedents from the British when they allowed this patent system to come out. A lot of these justifications have been post hoc.

One is that it encourages invention. It's said

that by giving proprietary rights to inventors we stimulate individuals to engage in this inventive activity in the first place. So we're encouraging creativity.

And not only are we encouraging creativity, not only do we set up individual incentives, we're setting up institutional incentives because firms and markets will devote resources to R&D. And they will do that because they know they will get a payoff.

This is said to solve a public goods problem. Public goods like information goods are not excludable. They're also nonrival. I think we can skip that nuance for the moment. They're not excludable.

They're like the lighthouse, or setting up a police force, or if you did as I lived in a large group house during law school, washing the dishes. If someone doesn't wash the dish, how can we determine who didn't do the washing and if I do wash the dish, how do I know that someone will use the dish and not wash it?

Well, I don't know and as a result I'm probably not going to wash the dish myself. We suspect there will be market failure problems of public goods because if I cannot appropriate the benefit due the invention, if others can freely copy it, then I won't do the work.

We would expect that people would allocate their

efforts into goods which have excludable properties, for example, like manufactured products. So this is said to solve a public goods problem. It solves the nonexcludability problem by doling out exclusive rights.

It also is said to encourage the disclosure of information. The chief legal alternative to the patent system is trade secrecy.

Trade secret holders are somewhat disfavored in the patent law. That's because they keep their light under a bushel. They simply don't tell others the benefit of the Coca-Cola formula or some other secret product.

And that's said sometimes to be detrimental to the public good because again the disclosure is not commodified. It's not printed. It's not made available in the patent instrument. And when the patent expires everybody can use the information to advance the state of the art.

In that vein, it also discourages the wasteful expenditures associated with maintaining trade secrets. It costs money to build fences and have guard dogs and have security guards and have safes. And we're not entirely sure all those expenditures are that efficient for society as a whole. Best to use the patent system, it's said, because that way we will avoid these wasteful

expenditures.

There's even more benefits. First, it's said to coordinate rivalrous R&D efforts by competing firms reducing the duplicative costs of R&D that's conducted in many firms.

Now, you can imagine that in a market there will be many entrants and many of these entrants all over the world are competing to come up with the same molecule or the same genetic material, or the same circuit, or the same antihypertensive drug.

And we like competition. We think that's for the good. But we also sense that there are inefficient races going on, that many parties are engaged in the same efforts. And that's somewhat wasteful. We're a little concerned that if that's overdone, then we're not being as socially productive as we could.

So in a sense, the patent system plays a coordinating function. Once a patent is granted, other firms and industries say, aha. This firm has got the lead. And they figured this out. Best not to engage in this effort. Or, I can at least improve upon it. I can take the information that's already been given and I can try to advance it myself but with the sense that perhaps this other actor has the technological edge.

So, in a sense, it plays a coordination function.

It's called the Prospect Theory where a firm stakes its claim to a certain, say, drug franchise or something like that. So again, the coordination function is said to be good.

The patent system is also said to stimulate markets. And that's because without property, how many markets can you really have? What the patent system does is commodify information. And once you have a commodity it can be traded.

You can imagine the basic problem. An independent inventor goes to a large firm. Hey, I've got a great invention. And the large firm says, well, what is it? Well, without a property right the conversation might stop. Sure you can use contracts and have nondisclosure agreements but they're imperfect substitutes for property because they require privity and property does not.

So there are several advantages to the property approach. Again, this reduces the transaction costs in bargaining because there are set reviewed property rights that have been subject to expert review that are believed to be valid patent rights and so we don't have to do duplicative efforts in determining whether a technology is really new or different or whether it's patentable. All that is a given. It's handed to us from the Patent

and Trademark Office. And so we can take that and bargain more efficiently.

It also reduces the need for firms to achieve complete vertical integration. That's the Schumpeterian hypothesis, right? Schumpeter, the economist of technological change, his grand prediction. First, he said get rid of all the lawyers but his other grand prediction was that that we will eventually go to a communist or socialist state because firms, if they have competitors in their industries, will never do an optimal level of technological advancement because they don't know that their firms won't simply steal their inventions.

Well, Schumpeter didn't really think a lot about the patent system because it turns out smaller firms can appropriate their inventions. And they don't have to be completely vertically integrated. They don't have to do the basic R&D. They don't have to get the invention to market. They don't have to do the advertising. They don't have do the warranties. They don't have to do the service. They don't have to do the sales.

They can do part of that and then they can sell these rights to another who can do the rest of the product or do the rest of the business that the firm in that industry needs to do.

So again, the patent system is said to reduce incentives for vertical integration. And that's good. Antitrust lawyers tend not to like complete vertical integration, at least that's what I'm told and so that can be for the good.

Well, those are all the good things I've told you, or some of the good things to which credit for the patent system is given but there's also been some negative commentary.

In fact, it's really the first time since the Great Depression you can actually read about the patent system in the popular press. And I would say the lay public doesn't seem that enchanted with us. In fact, there doesn't seem to be any legal limit on the number of times "patently absurd" can be used in a journal or editorial hype.

And why is that? What are people telling us about this? Well, it's said to increase industry concentration. It creates barriers to entry. The patent system is best played by the wealthy. It's best played by larger companies because it's a specialized regime that involves a lot of expertise.

And so this expertise often doesn't come cheap and that means that a large number of firms in established industries often have massive patent

portfolios built up, massive property estates, suites of evergreen patents. And it's hard for newcomers to come in and get that edge.

It attracts speculators. Some would say the Patent Office is a very porous agency and patent damage awards in patent cases are very high. That's a game that's ultimately irresistible and it's a game people want to play the patent game rather than engage in more socially productive activity. They would prefer to basically set up patent mills where the product is patents or dust off the dormant patent portfolios of others and assert them in quasi-champertous endeavors.

So these are concerns that have been articulated. The patent system is also a game industry can't afford not to play. Once an industry has said you're in the patent system. Hello, business methods, you're in the patent system.

If you're a participant in that industry you can't just say I'm not going to participate in the patent system, I refuse to be a part of it, because others are going to start getting patents and when the patent is asserted against you, you're going to need some kind of defensive property right to have a little bit of a bargaining position at the table.

You cannot afford not to play. You must play as

soon as one of your competitors starts playing. So everybody has to come in. It's not sort of a high road to the patent system. You take the low road of necessity.

It has in terrorem effects upon innovation. It's felt that perhaps if the Patent Office is too porous, these property rights will come out on inventions and the patent was just improvidently granted. It ought not to have been granted.

Well, you might feel pretty strongly a patent should not have been granted but it's not costless to get that grant overturned. The patent is entitled to presumption of validity and to overturn that effort involves a great deal of resources.

So rather than do that -- because it's been said that companies will often just not engage in the activity to which that patent pertains. And that obviously entails certain social costs.

There's a unified patent bar. Unlike the labor bar where there's the management group and there's the union group and once you're sort of in one of those firms you're not really going to cross the street so readily. The other side won't hire you.

And when there's discussion there's a very robust debate between these adherents who have their competing

views. That's not so for the patent bar. Most accused infringers are also patentees themselves. That's because everyone's on the cutting edge. That's why you're being sued.

And patent attorneys represent one client whether they're the aggressor or the accused infringer. So the patent bar tends to like patents. Once they're in it tends to sort of help their business to some extent. At least that's the common consent of the complaint. And there's not a lot of robust debate.

Also the patent system is a rarified discipline. It involves certain legal and technical qualifications. It was and perhaps still is a very obscure discipline. So there's more of a guild mindset, I think, than sort of other areas of public law.

Some might say the agency and the court have been captured. The granting agency perhaps has more workload, more flow, more regulatory ability, the greater the ambit of the patent system is.

And that may also be said to be so for specialized appellate court. We lack the laboratory of many different courts of appeals weighing in and having their views percolate about and eventually they come to the Supreme Court which resolves it for the good. Everything is sort of done at this lower plane and

perhaps that doesn't create a great deal of dialogue.

There's also a great deal of public goods problems associated with challenging issued patents. Suppose we're all competitors in one industry and I get a patent. Which one of you will act as the champion of the industry, stand up and try to invalidate my patent?

If you do, I'll probably sue you for infringement. Why are you doing it? You must have some interest. And if you do all that work, once the patent's invalidated everybody gets the benefit. Once you do the work your competitors can simply start marketing the once-patented good themselves.

So there's a lot of public goods problems there too. And so there often aren't the incentives to challenge issued patents. Best to let them lie. The short of the long for the pros and cons is that it's very difficult to quantify the social costs and benefits of the patent system. That's a reality.

A lot of these complaints are very qualitative. We don't know what would happen if we extended the patent term by one year, if it became 21 years. We just don't know. We have no idea. Economists just haven't given us a lot of information that is useful. Innovation is very hard to pin down.

I think the best comment I have heard yet is that

we don't have enough information to today abolish the patent system nor do we have enough information if we didn't have a patent system to start one. We're sort of stuck in this stasis because we just don't have a lot of quantification on what we have done. So take that.

I'd also say a lot of the complaints about the patent system tend to call not for its rejection but for its refinement. So in all events, those are some of the pros and cons.

Let me weigh in and do some of the substantive requirements of patentability. So I'm moving now from the policy, the big vision, and I'm going to walk into the weeds and say here are some of the requirements to get a patent. So here we go.

I am going to talk about four substantive requirements that occur and three of the 1952 Act provisions: statutory subject matter, utility, novelty, and nonobviousness.

Now, these are the four, the principal four substantive requirements. Now, it's not enough that your invention meets the requirements. You have to fill out a patent application with certain disclosure and claiming requirements too. But I'm going to pass that on to my colleague in the panel.

So let's talk about statutory subject matter

which I think is probably one that may be best known to people who wouldn't count themselves as patent wonks.

Section 101 says that a "process, machine, manufacture, or composition of matter" may be patented. Those broad words have very few inherent limitations. Look around you and if anyone sees anything that's not a composition of matter, please let me know at the break.

How about a process? What's not a process? What action, behavioral engagement, activity that you can think of is not a process? They're all processes, you know, how to prepare to give a speech. That's a process.

And I can articulate that in the fashion of a patent claim and try to get proprietary rights in it. I mean, that's just a reality. The words don't exude limitations on what can't be appropriated through the patent system.

But nonetheless, the courts gave it a shock, at least for a while in the history of our country. Now, a lot of these decisions are really old. They're sort of 19th-century decisions and judges seemed a little bit more confident of themselves than perhaps they are today. They just said it. They often didn't give a lot of reasoning. But they just said certain things aren't patentable and that's the way it is. And there wasn't a lot of logical development about why not.

So what developed are sort of a series of traditional exceptions to patentable subject matter. Laws of nature. We didn't get a lot of hints on sort of who or what nature was and what her laws were but it said, well, you couldn't patent the law of gravity or something like that, something that was just discovered rather than invented.

The Constitution says discoveries but anyway that's what the court said. Abstract ideas, something that's sort of an abstract, something that was too much of a breadth of thought that didn't have a particular embodiment, that too was said not to be patentable. We'll talk a little bit about that more when we get to the utility requirement.

The courts have said, well, patent law is about downstream products not upstream ideas. And there are some problems if you had an upstream idea. Let me hold off on that.

Mathematical algorithms with no practical application just abstract ideas, too fundamental to technical progress for one to appropriate.

Mental steps, something done through head and hand, not patentable. It had to be some kind of machine. This wasn't about sort of inchoate behavior.

Printed matter was said not to be patentable.

It's like well, we have got this copyright law and if you have some kind of work of authorship we ought to head them over there. That's a different set of rights and responsibilities and you really shouldn't get both. You sort of should pick one and we're doing the picking. And you're going over to the copyright system.

And of course the favorite one that's had a lot of recent notoriety is method of doing business. Methods of doing business, they're really a matter of social observation. They're not quantifiable.

If you went onto a university campus you really wouldn't go to the science department. You wouldn't go to the physics or chemistry or biology places. You would go over to the business side. And so that's not technical. That's not something that should be patentable. It can't be reliably repeated.

My methods of doing business, for those of you who were sort of outside the debate, I'll give you an example, one of my favorites. Pricing on the 9s. You know, it's really hard to buy something for $10 in this country, don't you think? Everything's $9.99.

And obviously, it's supposed to mislead gullible consumers who think they're paying less than they really are. And of course, I guess I'm among them because I just bought a tank of gas last night. If you think about

the nine-tenths. In Japan it's eight. I don't know why eight. I think it's considered a lucky number as the closing digit.

It's also said cashiers have to make change, and actually would have to dip into the cash register rather than just pocketing the money. It's supposed to prevent fraud, method of doing business, right, patentable or not.

Probably when it was invented there's a lot of antecedents that are said to go to pricing on the 9s but probably not patentable then. I would say probably patentable today, if indeed, it met the other requirements.

We have seen a lot of broadening in this area. The patent system has become increasingly ambitious in its grasp. Again, the patent system was traditionally about biology, chemistry and physics, the engineering disciplines associated with it.

Now, virtually every human endeavor I can imagine is subject to private appropriation through the patent system. There are no really inherent limits as to discipline, as to what can be patented.

In a sense, the patent system has become the ultimate regime of private regulation where one individual basically gets from the Patent Office a cause

of action in tort that it can enforce against its competitors for 20 years. That's the basic thrust of what I'm going to tell you now.

One of the phrases that's a very common mantra in our system is "everything under the sun made by man" may be patented. That supposedly was part of the legislative debate associated with the 1952 Act. And as you can suspect that's a very capacious phrasing. There's not much that's without that language.

Now, why does this matter? I mean, who cares? We've got these other requirements. This is just one step in the road, right, one gatekeeper. Why does it matter if it's a porous gatekeeper?

Well, it matters because the patent law offers a robust property right with few restraining principles. It basically is an in rem right. It's a property right. And unlike, say, the copyright law, copyright you have to copy, you have to derive to be an infringer. The copyright law means what it says. It protects against copying. But that's not so for the patent law.

Even an independent inventor, someone who didn't know anything about that patent, someone who didn't even know about the patent system, they can be held to be infringers.

You can bring a patent suit the day a patent

issues with no notice, opportunity for comment, all the protections of administrative law that as lawyers we're used to. None of those attach to the patent system. You can bring a suit the day the patent issues.

It matters what industries we tell are patentable, have patentable advances. It's important. There are very few allaying doctrines that ameliorate the thrust of this right.

Copyright law has a fair-use privilege so I can quote for purposes of news reporting or commentary. But that's not so for the patent law. There is no fair-use privilege. There's no experimental use privilege, at least beyond a very nascent, ill-developed principle from a few early cases in the 19th-century. You're not allowed to experiment. That too would be an infringing act.

And there's no effective misuse doctrine. Misuse is sort of a pre-antitrust doctrine that essentially acts like antitrust. It was more broad, no market power showing, for one thing. But that too doesn't pertain anymore. All these doctrines have been stripped.

So it matters what we put into the patent system. This isn't something that like copyright law, oh, let's let it in. We've got fair use. We have these compulsory licenses. That's not true in the Patent Act. There are

none of these restrictions.

Once an industry is subject to the patent system, again, participants in that market get the ability to regulate each other. That's what the patent system does. It's a system of regulation. And I think careful thought ought to be had about whether different industries should be associated with this or not.

Now, some examples of the broadening trend -- or just two cases. There's a lot of cases. One is Diamond v. Chakrabarty. And this was Annanda Chakrabarty's oil-eating bacteria that you would pour into a harbor, for example, the waters of a harbor, and eat up oil slicks.

And there was a lot of discussion whether living inventions should be patentable subject matter or not. And the Supreme Court said in a very robust case in 1980, very magisterial opinion, that they were. Just because something is alive doesn't mean it can't be patented.

What about computer software? Well, that's been a notorious point for the U.S. case law. Software looks like text so it looks like script, written material that would be subject to the copyright law but it's really a machine. It's a machine that is built with text.

And as a result it's sort of functional as a machine too. So there's been trouble about whether we ought to put it in copyright or patent. And the

copyright was decided rather early on. The Federal Circuit said well, patenting is okay too. And then one case was In re Allappat.

Let's talk about methods of doing business because I think that's probably most important to the kinds of things that are done or are of concern to antitrust lawyers. And also it's the most recent development. You probably have heard something about this.

Traditionally, not patentable or at least I would say there's a good body of law that said it was not. In Ex parte Abraham, which is a Patent Office commissioner opinion, says there's no patents for methods of bookkeeping.

In a CCPA case, that's the Court of Customs and Patent Appeals, a predecessor court to the Federal Circuit, that court said that the Constitution opposes exclusive rights to engage even in ordinary business activities.

It referred to the Statute of Monopolies, a predecessor or sort of real starting point for common law patent systems. And the Statue of Monopolies was, in part, really motivated by the Crown doling out exclusive rights in business methods. And Parliament put a stop to it. And this court in 1951 felt that the constitutional

language reflected that motivation.

Judge Rich, a famous Federal Circuit judge, really a leading patent jurist, who later writes the State Street Bank case, wrote in a law review article in 1960, no patents for one of the greatest inventions of all time, the diaper service. What he was referring to, I think, was sort of the trucks of cloth diapers that would be delivered and picked up on a routine basis.

So these were the traditional views, not patentable subject matter. But these traditional views ran into the broadening trend for patentable subject matter.

Now, Signature obtained a patent, and Signature is a player in the financial services industry, they got a patent on a data processing system and I'm quoting from the claim, "for managing a financial services portfolio established as a partnership."

Now, the financial services portfolio was a so-called master feeder fund, a fund of funds. And it turns out that the IRS and Congress have given certain tax benefits to master feeder funds if certain accounting regulations are complied with.

So if, for example, on a daily basis you submit profits and losses and ownership and how many shares, et cetera, can be done. You do that on a daily basis you're

treated as a partnership which means one-pass taxation as compared to, say, a corporate model where there's double taxation. So that's the concept.

So what Signature did is invented a very robust computer system for tracking that. Many of these funds, these master feeder funds are huge. So if you mean to comply with the regulations and either hire a Rain Man, you know, an idiot-savant who can do it for you every night in his head, or you've got to get a big computer to do it.

Now, what Signature's claim said was I've got a computer and it can perform the following functions. And the functions are calculating ownership, calculating the profit and loss each day, calculating what percentage of what is owned.

And if you look at the Treasury regulations they're really almost the same. It seems pretty clear that whoever drafted this patent claim read the Treasury regulations and then put a computer for doing the Treasury regulations.

And that was the claim. It's a very broad functional claim. It's a computer but it's not drawing structurally how the computer is organized. It's defined by what the computer does.

Now, Signature went around telling -- at least it

is reported that Signature went around telling other members of the industry well, if you'd like to get this tax benefit, you really ought to buy my computer. Oh, and by the way, we have a patent if you don't.

So State Street Bank, another player, brought a declaratory judgment against Signature. Well, the trial court, Patti Saris, struck down the patent on two alternative grounds. One is it's math. You're just doing math. You're just doing accounting. And it's very simple math. It's kind of unworthy math. It's just arithmetic.

Second, it's just a method of doing business. Remember Ex parte Abraham and methods of bookkeeping? Well, this is just a method of bookkeeping and that sort of thing ought not to be done through the patent system.

And on appeal the Federal Circuit reversed the trial court in very sweeping language. This was not a narrow case on very narrow grounds. Very broad and robust language was used that really sent a shockwave into the patent community.

Judge Rich says, Well, patentable subject matter should focus on the essential characteristics of the subject matter, in particular its practical utility. And he reasoned the transformation of data by machine through math produces a useful, concrete and tangible result and

is therefore patentable.

So basically, that seems to be the test, a useful, concrete and tangible result. If what you're claiming does that, it's patentable. That seems to be a pretty lenient stricture. If it's not useful, why get a patent on it?

And as we'll see, there's this separate utility requirement that seems to be the same thing. It seems as if this patentable subject matter has been collapsed into the requirement we'll talk about next.

But the case goes on and says, well, not only is it not math, we're going to get rid of the business method exception because it's ill-conceived. He said whether an invention is patentable should not depend on whether the subject matter does business instead of something else.

Well, there's been a lot of repercussions. The fact is a lot of industries have moved from a trade secret model to a patent model. Of course, since they're embodied in computer hardware the Internet-based business community went over immediately because there it sort of looks like technology. It's got circuits and there are interfaces and so it looks a lot like what was patentable before.

One of the more famous cases is Amazon.com one-

click patent. What the patent claims is a method of selling an item on the Internet and what you do is first you're supposed to put in or give the system some sort of indicia of payment, so your credit card number, and also identification indicia, your name and address.

And at that point you are then empowered through a single action, like one click of a mouse button to order items on the Internet.

So Amazon gets this patent September 1999. They filed suit against the rival e-tailer, barnesandnoble.com, and get a preliminary injunction from the Seattle district court on December 1st, 1999 on the eve of the all-important holiday shopping season.

Now, the Federal Circuit declined to intervene but eventually on February 14th, 2001 lifted the preliminary injunction reasoning that the patent was probably improvidently granted.

This encountered a great deal of criticism. Has anyone here used a vending machine? Have you given the system indicia of payment and then did one-click ordering? I sure have. How about a bar tab? Hey, give me another. Right? I mean, is putting it on the Internet patentable? Is somehow placing on a computer everyday business activities the sort of thing that we ought to do?

There's also concerns over consumer lock-in. Patents don't have to be enforceable that long to have significant market price effects. If I am a customer, and I'm an Amazon.com customer, I know where the search window is and I know how it works. I have entered in the addresses of my cousin from Kansas City and all this sort of thing.

If I'm going to buy them something I just go to Amazon. I don't go to other places. Plus, I like one-click ordering. So, okay, I'm lazy. I like one-click. And only one company can do it. So I'll go to Amazon and I'm going to enter in laboriously my credit card number and addresses.

Even though the patent fades, I'm still going to stay with that one company because some relationships are sticky and you stay with that company. So this kind of lock-in means that you don't really have to have the whole 20 years to have some value in an exclusive interest.

Now, the patent -- I often like to let patents speak for themselves and if time allowed and I was more PowerPoint savvy I would have done what my colleagues appeared to do and scanned in some cover sheets and some patents.

But rather than poke fun at anyone else's

proprietary right at this point I will simply note for you that the patent system has become very ambitious at this point, accounting, aesthetic arts, methods of painting, architecture, finance, legal compliance, marketing.

I don't know that the patent has issued but I have actually heard that there is a patent that's been filed on a method of determining whether regulatory authorities will approve your merger. So I don't know if they looked at the merger guidelines and went from there but I've heard that that has been sought.

Again, the patent system seems to be the ultimate system of private regulation. There is no industry that seems to be wholly exempt from the patent system. And that has certain consequences. These decisions may seem like an obscure issue but it matters in my view.

Let's move on to the utility requirement. I said before something has got to be patentable subject matter but it also has to be useful. It has to fulfill this utility requirement.

And generally that's a very lenient standard. Something has to be minimally operable for a known use. It doesn't have to be better. Have you seen all those television commercials? It's our patented formula. Well, they're not really telling you very much. It

doesn't have to be better than the prior art; it just has to really be different. That's what the patent system is all about.

The patent system is generally not considered the place for technology assessment. It has to be different but it doesn't necessarily have to be better or considered to be better in particular domains.

Now, actually, I must say of my three colleagues here I'm easily the least-qualified to speak on this because I think I'm the only one without a Ph.D. for one thing.

Actually, of my three colleagues, I'm the only without a Ph.D. in the life sciences or biology. But I'll give it a fair shot. Maybe it's my advantage because I'm more on the lay person's level and they can pipe in as they wish.

The utility requirement plays a larger role in unpredictable arts like biotech and chemistry. And the reason is there in those fields further testing is often needed to determine whether a compound that was developed has actually any uses at all.

Now, my background is electrical engineering, so I would sort of go trotting off with my circuit and it's a predictable art. I would know what would happen if I put a resistor in a certain place in the circuit but

didn't know that well; I wouldn't say I was that accomplished at it. But anyway, I can figure it out.

That's not always so for, say, pharmaceuticals. Suppose I'm a pharmaceutical company and I have a drug that is a great antihypertensive agent but it also makes people lose their hair and it has other problems. Well, what should I do?

Well, what I might do is take that compound and tweak it a little bit, change its structure a little bit, and see if I could still have the beneficial properties without the bad.

Now, when I do that, chemistry is a very unpredictable art, at least some of its disciplines. You should see polymer chemistry. I think that's the real black art and nobody knows really what's going on in it.

But if you tweak the shape of the compound its behaviors may become very different. It may no longer be an antihypertensive. It may be inert. It may have other properties. And figuring out what exactly it does is going to require some further testing.

So you don't really know whether it's useful or not but you'd like to get a patent on it as soon as possible. You'd like to file the patent application promptly because maybe your competitors are doing the same thing and you don't want to be whipped in the race

to the Patent Office.

So what happens? Well, when they seek patent protection a little prematurely the utility standard may intervene. The leading case is Brenner v. Manson. Brenner is the patent commissioner. Manson is attempting to get a patent on a method of making a steroid that was similar to a known steroid with tumor-inhibiting properties.

But at the time he filed his application Manson actually didn't know whether his adjacent homolog, this very similar steroid, really did anything. It was close to something that did work but he wasn't really sure if his did anything in particular. He hoped it did.

What did the Supreme Court say? Well, it upheld the rejection of the application. And probably the key line from the opinion is, unless and until a process is refined and developed to this point where there is a specific benefit that exists in currently available form there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

So again, specific benefit, currently available form. Why does this requirement matter? Well, we're concerned about patenting too close to the laboratory bench otherwise concerns arise over the tragedy of the anti-commons.

I know in particular Scott Chambers has had some views on this, but most of us, if we have science or legal training, are familiar with the tragedy of the commons, that is why are whales, for example, endangered?

Well, because no one has a property right in the ocean. So no one has incentives to be very judicious in their harvesting of that crop. It's best just to get in and take what you can. If you're judicious and only take so many, who knows what the next whaling ship or the next country will do. So as a result, there's no property. There's overexploitation.

It could be so as well for patents for the anti-commons problem. And that is too many property rights, underexploitation. If we allow too many people to get patents too early on on upstream ideas or upstream intermediates that are not related to the final product, there's going to be a lot of property rights to try to get anything on the market.

You might have to deal with five or six other people. That leads to a lot of inefficiencies because of bargaining that is necessary to get a product in, plus a lot of people will have their hands in the purse. Plus, if there's five patents on something by five different parties and you manage to get four of them in your bargaining, what's the fifth one going to do? Well, game

theory teaches us they're going to engage in hold-up behavior and try to get a bigger cut.

So there's some problems. So if we have too many property rights, we're worried about the anti-commons. Again, the patent system has traditionally been about downstream products not upstream ideas. And so we're trying to enforce that more by saying something has to be useful. There's all that thing about transaction costs and hold-up rights.

Well, the rigor of the utility requirement has just been up and down. This has really been a complex story but there's a case from the Federal Circuit called In re Brana, 1995, that's probably that court's leading utility case. And it seems much more immediate than Brenner v. Manson and surprisingly it doesn't even cite Brenner v. Manson.

But what it said in that case, it was also a tumor-inhibiting compound, and the court says, among other things, well, there's nothing inherently unbelievable that chemicals can be used to cure cancer. So let it up. And that seems much more flexible than what the Supreme Court had said earlier.

The PTO has put out two utility guidelines on this, or they have revised them twice in recent years. And, actually, again, Scott is very knowledgeable in

this. But the first phase was more in keeping with Brana, more liberal. But the second ones that have come out more recently seem to be more robust and seem to be returning to this Brenner v. Manson format.

An interesting issue is will the Federal Circuit uphold those guidelines? But what do those guidelines say in a nutshell? And again, I'm going to move quickly because I think my colleagues can speak better to it. Under the new, improved utility guidelines, the applicant has to demonstrate either a specific substantial and credible utility or a well-established utility.

And what this means is the utility that's mentioned cannot be at a very high level of abstraction. You can't say, well, mine is useful for research or this class of compounds has been very helpful in this area. It's got to be specific to that compound and to its specific detailed use.

Also, you can point to a well-established utility, if something is well-known within the art. One thing is you only need to have one utility. Suppose you come up with nitroglycerin and you say, you know, it's useful as an explosive. So you get a patent on that for the period. If someone else realizes later nitroglycerin is a wonderful heart medication, your patent still reaches to its uses as a heart medication until it

expires. You only need the one use to get a patent for all purposes.

Well, that's utility.

MR. COHEN: Before you move off utility, perhaps if you could just -- you or Scott or Lawrence or any of you -- would like to give us just perhaps a quick example of each of the three standards, the specific, substantial and credible, something that wouldn't meet that.

PROF. THOMAS: Scott, could you do that? I'm getting tired of hearing myself talk.

DR. CHAMBERS: For a specific utility you can think of somebody, and this was actually from a case, they applied for a patent and their claimed utility was for its biological use.

It was a particular compound that was going to be used in the body but they didn't say what that biological use was. It was too general. It wasn't specific enough. And the CCPA, which was the predecessor of the Federal Circuit, said it's not acceptable to give some generalized use. It's got to be specific.

If someone said in the present context, I have a very precise sequence of DNA. Here is the sequence. And I can use it as a carbon source for bacteria. Well, gee, that's not specific enough. The fact that you can use anything that has carbon in it as a carbon source is too

generalized.

Now, for a credible utility, it would be something that would be when you stated it it would be pretty clear to one of ordinary skill that it was not credible. I have a particular compound. It restores youth.

Well, that sounds a little odd. It may be that there are certain vitamins that can help with the strength of a membrane. There can be a lot of things that go to restoring youth but a simple pill that's going to restore youth, that sounds a little incredible.

And as far as the substantial utility, if you created a transgenic mouse and you said, I'm going to use this mouse as snake food. Well, that's not really substantial utility. Any mouse will do that. There's nothing that separates that. So those would be three general examples.

MR. COHEN: Terrific.

PROF. THOMAS: Okay, great. Let me march on then and do the novelty and nonobviousness requirements. Now, to be patentable an invention must be new. I think everybody realizes that. It's got to be new.

But what does new really mean? Well, it really just means different. It's got to be different from a single source of public domain knowledge. That's the

concept. It has to be different in at least one dimension from a single reference that's come before.

Now, when I say public domain knowledge, regrettably that is not easy to determine under U.S. law. There's a very complex and subtle definition. And that's given to us in Section 102. This isn't the place to go through Section 102 in detail.

When I do it in my class I call it The Long March and spend about a third of the semester wending through every nook and cranny of a statute that really is not in a very good logical order and as subsequent patent acts came along Congress sort of shoveled a new provision on at the end. And they kind of overlap a lot and it's tricky.

But a couple of fundamental notions will get you a long way. One is that the U.S. is a first-to-invent system. And that means we're very concerned about which party was the first in the real world, in the laboratory bench, in the garage, wherever, to actually have invented what's being claimed. And so that is the general rule.

First, if there are two competing inventors who file at the same time, roughly at the same time for the same invention, the first to invent in the real world is the winner.

It's very different than for every other patent-

granting state which basically says the first person to file at the Patent Office. So again, other countries say it's the first person to get to the Patent Office prevails. In the U.S. it's the first to actually have done it in the field. When something is filed is helpful but it doesn't control the issue.

Now, in addition, if there's a reference that comes out, say a journal article that discloses the invention, and the inventor files later, say the day after, if she can show that she invented prior to that reference date, she can antedate the reference and that reference will not apply either as public domain knowledge.

There's a problem with first-to-invent systems and that is that there's not much incentive to file a patent application in a first-to-invent system because once you're the first inventor you've got it. You're the one. I'm the first inventor.

So you could just sort of hold back, not file, wait until somebody else invents it and files and then claim your right at such time. You can be spurred into filing but if you're the first inventor, you've got the status, right?

So the Patent Act has to sort of account for that and one way it does that is through the statutory bar.

And this is good old Section 102(b). And what this says is, if certain acts occur more than a year before the filing date, the patent will be barred. It will be rejected.

And what are the statutory bars? Well, they are public use or sales of that invention in this country, in the United States, or the invention was subject to a patent or was described in a printed publication anywhere in the world.

Now, these sales, uses, patents or publications, they have to be, to be defeating, they have to be enabling. In other words, it's not enough that if someone actually comes up with a transporter, wow, let's transport people down from the ship to the surface of the planet, the Star Trek show is not going to hurt that patent because it's not enabling. It's speculative and it doesn't describe how it can be done.

So it has to have this teaching. There has to be a full teaching how to practice the invention. And in some arts, predictable arts, mechanical engineering or something the teaching can be pretty light. But in the unpredictable arts there has to be more showings. So something like biotech or chemistry, more.

Now, the patent system has a difficult series of rules interacting with trade secrets. And these also are

not easily digested. They're not really amenable to quick summary. But the short is the patent system doesn't like trade secret holders. It flip flops depending on who the trade secret holder is.

If I'm the patent applicant and I commercially used the invention as a trade secret for more than a year before I file, I'm barred but if I'm the patent applicant and it is learned that someone else used the invention as a trade secret, I get my patent and that other person becomes an infringer. So we incent trade secret holders to get into the patent system promptly.

The risk of a trade secret holder is that an independent inventor comes along later, gets a patent and renders that individual an infringer. So that's something to remember. The patent system doesn't really like trade secret holders that much and so their trade secrets don't defeat the patents of another but at the same time if you're a trade secret holder you yourself are unable to get a patent if you commercially used for more than a year before the filing date.

There's an even trickier rule which is Section 102(e) and this rule says that U.S. patent applications that issue from the Patent Office have a prior art effect of this date, not of the date they issue but the date they were filed.

And what this means is when I file an application the Patent Office traditionally kept all of the applications secret. I think we'll get more into that with my next colleague. These were held in secret. Once the patent issues it has a prior art effect of this date of the date it was filed.

And this was done in the famous Milburn case and actually Justice Oliver Wendell Holmes Junior came up with this rule or at least proved the rule. And what he said is delays of the Patent Office ought not to cut down on what was done.

So the processing time between the time an application is filed and the time it is published and formally issued are basically ignored. This creates a category of secret prior art of pending applications as they wend their way through the Patent Office.

Well, some of those points are pretty technical. Let's move on to nonobviousness which is the last requirement, mercifully, that I will dangle in front of you. That's Section 103. I said that novelty is fairly strict but nonobviousness is a more general requirement and to be honest at this point for most inventions it's the most significant gatekeeper to patentability.

Sure, in biotech and some chemistry areas utility is probably more important but for most inventions -- or

at least as important -- but for most inventions nonobviousness is what is really going on.

It's a funny term but what is says is, under Section 103, no patent may issue "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art..."

So looking at what a skilled artisan in the field would know, would she be able to come up, using public domain knowledge, with the invention. It's not enough that the invention for which patent is sought is just strictly different in one way from one reference in the prior art. It's got to be, in addition, nonobvious over that state of the art.

Now, this allows reference combination. The patent examiner could take a teaching from one reference, a journal article, a teaching from a prior patent and, if there's motivation to combine them with a reasonable probability of success, put them together and say, you know, if I take this reference and this reference, it's just taught everything you're trying to do. And that would be a ground for rejection.

Now, nonobviousness descends from an earlier requirement which was called invention. Don't use the

word invention in this context around patent attorneys because it's sort of become a dirty word in the community. This was just a very amorphous and vague standard.

Some court said you had to have a flash of genius. If you were plodding in a research laboratory and after slow experimentation and use of a lot of resources and came up with the invention, that's no flash so not patentable.

Synergy, the parts of the combination have to somehow achieve a result greater than their sum which is pretty hard to do other than in rhetoric. There had to be something unexpected or exciting. I think that case had to do with floor tile and the court said there's really not that much unexpected or exciting about floor tile.

One court even called it, I think it was Judge Hand, called it that impalpable something which didn't really give industry a lot to go on when they were trying to figure out whether to file a patent or not.

So Section 103 negates that standard. I went a little fast. But Section 103 negates that standard and says well it doesn't really matter how the invention was made. You don't need flash; you don't need synergy. The standard is nonobviousness.

Now, the big case on this is the Graham case from the Supreme Court. And the court said, well, let's put some flesh on the bones of Section 103(a). It says we have to judge nonobviousness from the perspective of a skilled artisan but we should look at these four factors: scope and content of the prior art, differences between the claimed invention and the prior art, the level of ordinary skill in the art, and secondary considerations such as commercial success and long-felt need of the art.

Scope and content, again, what does the public domain knowledge teach. What are the differences between that knowledge and what's being claimed. What's the level of skill in the art?

Is this an area of art where you need a Ph.D. and a couple of years of post doc experience to operate at the cutting edge or is this a dumb art like basket weaving or kitchen appliances where we can expect artisans to really be able to grab references from different fields and combine in interesting ways.

And also secondary considerations. If something is commercially successful that suggests that, hey, this was a pretty good invention. Long-felt need, if the art had long clamored for an invention that had these traits then that too suggests that it would not have been obvious.

Now, there's some disfavored frameworks for nonobviousness. Obvious to try is one of them. Obvious to try occurs when there is a prior art reference that says, you know, it would be a great idea to experiment in this area but you know there's about a million compounds out there and one of them might work and I really don't have any methodology for telling you which is the good one but it would probably be a good idea for someone to take a look at this.

Well, that's been called obvious to try. It's obvious to try it but it's not obvious which one is the right one. So that's been held to be disfavored. You're not supposed to say, well, this would have been obvious just to try it.

Hindsight, that's the classic comment. You're supposed to look at nonobviousness based on the prior art not today. Time passes between the time an application is filed and the time an examiner considers it. The patent issues, more time passes before the litigation. You're supposed to look at the prior art that pertains to that patent, not what we know today.

Also, when you combine prior art references you have to have some motivation to combine them. It's unfair or impermissible, it's been said, to take disparate prior art references from many different fields

and somehow miraculously combine them to achieve the invention.

Inventors have to have some motivation, motivation from their teaching of the references, motivation from the discipline that would allow them to put this disparate teachings together.

Why are these important? Why do we care? Well, we want to preserve a patent-free zone around the state of the art. We want practitioners to be able to practice using their ordinary skills, say a mechanic, and you want him to use his ordinary skills and not just through his ordinary exercise of everyday skills suddenly infringe a patent. They need to be to do what they can.

And we want to preserve the public domain. Not only that, we don't want to take anything out of the public domain. That's a big no-no in intellectual property. Once it's in the public domain you don't take it out.

There are investment back expectations. People think that this invention can be practiced. We don't want to rip that away from them. Also, with the patent system, when patents expire that knowledge enters the public domain. So we're increasing the storehouse of public knowledge.

Finally, libraries not laboratories. We invent

something or we're considering doing something, we want companies to look to the storehouse of knowledge rather than trying to do it all over again themselves. So they recognize, oh, boy, we have to invent something new, a new compound.

We want them to look in the knowledge base, patents, publications, et cetera, rather than just marching off to do it again. We expect that that's more efficient. So if we say that something has to be novel and nonobvious to be patented then what we're saying is that for someone to do something new they may well -- this may be something that's already patented and they should look there first.

I'm not sure that explanation came out entirely the way I planned and I have also, as always, taken a little longer than I had thought but I'd be happy to turn the lectern over to our organizers. Thank you.

MR. COHEN: I think what we'll do is we'll take up a few questions based on Jay's presentation and then we'll take a ten-minute break so everybody can relax for a little while.

I would start us off with one question. We have heard in the nonobviousness context that some of these secondary considerations have been given more and more weight. Commercial success is one.

Could you talk a little bit about what kind of showing has been needed to demonstrate a nexus between the actual invention that was accomplished here and the commercial success?

PROF. THOMAS: What the Supreme Court said in Graham is that secondary considerations like commercial success may have relevancy. The Federal Circuit seems to be putting more weight on them and has said they really ought to be considered in every case. So it's not may; it's shall.

A difficulty with that is that if there's a patent litigation there's going to be commercial success. Either the patentee or the accused infringer is enjoying commercial success. Given the transaction costs of patent litigation you're not going to go after something that's not making any money.

So there's a requirement to show the commercial success isn't just floating around or associated with the reputation of the company, its advertising, that it is a convoyed sale with a more fundamental good. There has to be a nexus that people actually are buying this thing because of the technological advance, because of the patented advance.

MS. MICHEL: Jay, I just wanted to highlight one point that you made about what the patent right really

is, and I think you described it as a ticket to court. I think that's an interesting description in the sense that it brings out the point that the right to exclude is the right to exclude those that a court has said infringe. Do you think it's a fair statement to say that there's no right to exclude those you accuse of infringing?

PROF. THOMAS: Yeah. The court will ultimately decide infringement issues. I mean, most rights we know don't enforce themselves. They have to be enforced by someone.

But I would also note that, of course, patents that are issued bear a presumption of validity and they often impact the way enterprises behave. The fact is that if there's a substantial patent suite around a drug, there's less likely to be generic competition.

Even though those patents haven't been enforced they are a barrier to entry into that market. They can act that way. Now, maybe if the patents are properly granted and we think the patent system works, then it's a good barrier to have.

So I don't necessarily mean that term in the pejorative. I wouldn't say that patents have to be enforced to have weight. Does that work for you?

MS. MICHEL: I think that's a good point. If I'm a patentee asserting my right to exclude I just wanted to

clarify to what extent that right actually encompasses the right to exclude others, to really exclude them.

PROF. THOMAS: It's an inchoate right.

MS. MICHEL: That a court hasn't ruled on.

DR. CHAMBERS: But it also has an in terrorem effect.

MS. MICHEL: Absolutely.

DR. CHAMBERS: If you go in and you accuse someone, that starts the damages period. And if they are willfully infringing, that is, they knew about this patent and they're continuing to do it, they can end up with treble damages. That's significant.

So while you may have to step into court to get them to stop you might be able to get them to stop just by letting them to know that you're ready to go into court.

MS. MICHEL: You're talking about a deterrent effect in that situation?

DR. CHAMBERS: Yes.

MR. COHEN: Okay. I think it's time to take a ten-minute break and then we'll resume.

(Whereupon, a short recess was taken.)

MR. COHEN: Our second lecturer today is going to be Scott Chambers, an attorney with the Washington,

D.C. office of Arnold and Porter where he practices intellectual property law.

He's an adjunct faculty member at Georgetown Law Center and the George Washington University Law Center. He's written and lectured on legal topics relating primarily to intellectual property protection and biotechnology.

Prior to joining Arnold and Porter, Scott was an associate solicitor at the Patent and Trademark Office. As such he worked extensively on drafting and implementing the utility and written description examination guidelines.

Before that Scott served as a biotechnology patent examiner. One of the factors that made him eminently qualified for all this is the fact that Scott holds a Ph.D. in molecular biophysics. So I'm going to turn the lectern now over to Scott Chambers.

DR. CHAMBERS: Thank you for inviting me. I'm going to move away from the high overview that Jay gave us down into the weeds of one other section of the patent act and then I'm going to tell you a little bit about how patents are obtained, what the actual procedures are.

Now, Section 112 is part of Title 35 and it's very important for new technologies because it both limits a claim to the ability to practice the subject

matter and it also makes the applicant show that the applicant actually invented a particular item.

It may seem strange to say that an applicant and later a patent holder might be questioned as to what he actually invented but the prosecution process from the time of filing to the time of obtaining a patent is very long. Sometimes little bits of additional information, key information, can find their way into an application and so Section 112 limits that.

It's important because the dates of priority in the patent system are tied to compliance with Section 112, first paragraph. Section 112, first paragraph reads that the specifications shall contain a written description of the invention and of the manner and process of making and using it in such clear, concise and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected to make and use the same and shall set forth the best mode contemplated by the inventor for carrying out his invention.

So this paragraph imposes three requirements on obtaining a U.S. patent. One, enablement, and I'm going to explain that a little bit; written description, which I'll explain; and best mode.

Now, the enablement requirement assures that the

public is actually in possession of the invention. Has the specification that was filed put the invention into the hands of the public as of the filing date.

The written description requirement assures the public that the inventor actually had possession of that invention when he filed the application. Has the specification taught when it was filed that the inventor had the invention in his or her hands.

And third, the best mode requirement assures the public that the inventor disclosed the best method that he or she knew about when they filed the application.

Now, the specification is generally written in a rather technical form. It's written for one who has got some skill in that art.

Now, the standard, as I have mentioned, is whether or not the specification allows one who has skill in that art to practice for the full scope of the claim. The claim can be covering a very large number of embodiments and the question becomes have you enabled not just one or two embodiments but have you enabled the full scope of that claim.

Now, it's not necessary to satisfy the enablement requirement to describe what's well known but it's a moving scale and by that I mean it changes with time and it changes with field.

By changing with time as more knowledge comes in and people are more aware of certain things, that which is well known and a matter of common knowledge becomes well known and it's not necessary to put that in the application.

Similarly, it changes with field. What is normal and expected in that field is going to be the determining factor as to whether or not something was undue experimentation.

For example, it might take six months to go from a particular patent application to an actual embodiment that worked. If that was six months in the construction industry, that may well be undue experimentation. But six months in the biotechnology industry is probably not a very important time frame because everything in that field takes six or 12 months.

Now, the 112 requirement limits the scope of the claim to what the inventor has actually taught or shown how to make and use for the full scope of each and every one of the claims. They have to enable that claimed invention as of the filing date.

In other words, even if the patent is issued years later and even if more information came to be publicly known during that interim period between the filing and the issue date, that's irrelevant. All that's

relevant is when it was filed, was it enabled. Did it put it into the hands of the public at that point.

In In re Wands the Federal Circuit set forth a number of different criteria to determine whether or not an invention that was disclosed was enabled. These are often referred to as the Wands factors but they are also used in interparty disputes where the fact finder has to look at these particular factors to determine whether or not the invention, when it was filed, was actually enabled.

The first on that list is the breadth of the claims. And the breadth of the claim simply sets forth the idea that if it's a very narrow claim, it may well be easier to enable than if it's a very broad claim. That makes sense. If you're just going after a very narrow property right, you don't have to show nearly as much as if it's a very broad property right.

The second factor is the nature of the claims. The third factor is the state of the prior art. Certain arts that are established you don't have to have quite as much information because what is already known plus what you have disclosed is enough to allow you to practice the invention.

Other arts, such as a new technology, those are going to require a good deal more explanation if you're

going to go after a broad claim.

The ordinary level of skill is the fourth factor that's required and that simply points out that if the ordinary artisan in that area is a Ph.D. chemist, you can expect that they're going to know how to do experiments. You're going to expect that they can do a lot more experimentation and make more leaps to other areas that would be necessary to practice the invention than if the level of ordinary skill was a high school graduate. So those are considered to be important as to whether or not the invention is enabled.

The fifth factor is the level of predictability in the art. Those arts that are predictable, such as the mechanical arts, don't really require much more than a drawing or an explanation of what goes into it. Other areas such as physiology or catalysts in chemistry are going to require a good deal more because those areas are not very predictable at least they haven't been up to the point of filing.

The sixth factor is the amount of direction provided by the inventor when the inventor provides a lot of material, a lot of formulas, a lot of indication of how to practice the invention it's going to be much more likely to be enabled than if the inventor provided very little information.

And the seventh is the existence of working examples. When you have not provided any working examples you're in a situation where if the examiner challenges you with good reason then you're going to have to show that you could practice this invention in some method. It's not necessary, of course, to have working examples but often a working example can be evidence that certain aspects of the invention were enabled.

And the eighth factor seems to be an adjoining of all of them which is basically the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Now, some examples of this are cases such as United States v. Teletronics which was 857 F.2d 778. And it was a 1988 case and the Federal Circuit determined that even spending $50,000 and requiring experimentation of six to 12 months was not undue experimentation in that particular field.

However, in a biotechnology case, In re Wright which was 999 F.2d, 1557 which came out in 1993, the claims were directed to a vaccine for an RNA tumor virus. And the applicant provided examples of RNA tumor viruses but the claim was written so broadly that the examiner recognized that RNA tumor virus, one that was in the news right then was the AIDS virus, and that a vaccine for

AIDS was not presently known and it seemed to be an intractable problem at the time. For that reason, since the claimant covered a vaccine for AIDS, they weren't allowed to get that patent.

It's interesting to note though that if they had changed the claim slightly so that instead of saying a vaccine for AIDS, which is a composition that confers resistance or protection, if they had instead asked for a claim that was more narrow, such as a composition that would raise an antibody to AIDS they could have gotten nearly the same kind of coverage, nearly the same kind of protection and at the same time it would have been enabled for that.

Now, enablement issues arise in new and rapidly moving fields because there's not much known about how to practice through broad scopes and also because the claims and the specification are going to be written not only by the inventor but also by the patent lawyer.

The patent lawyer probably doesn't have an idea about a new field what he should be claiming or the breadth of the invention and so he's going to claim as broadly as he possibly can just to avoid any suggestion of malpractice.

At the same time, the inventor doesn't understand the patent laws so he's going to go along and defer to

the attorney. The end result is a lot of times in a new field you'll have very broad claims which are sensitive to attacks for enablement.

Now, when the application comes in there's a presumption at the Patent and Trademark Office that it is enabled. Unless the examiner can come up with evidence or some reasoned argument to suggest that it's more likely than not that it is not enabled, that application and those claims are going to have no problem with enablement.

You have to keep in mind that the Patent Office has no testing facilities so what the examiner is going to be looking for is evidence that something didn't work. In science you often publish what does work. It's not quite as common to publish what doesn't work. So there can sometimes be difficulty in coming to that bar.

In certain technologies, in particular in biotechnology, it is sometimes necessary to have very specific starting materials such as if you're going to make a particular gene you might need to have a cell line that had it or if you want to raise an antibody you might have to have a cell line that raises that antibody.

For that reason, to enable the invention you can sometimes resort in certain technologies to providing a deposit of the organism with a recognized depository that

will provide that to the public freely.

And that's the case in biotechnology. If you have a need for an organism you can provide it to the American Type Culture Collection or a number of other repositories and they will provide it and that will allow you to still be enabled because as of the filing date you have to be able to show that the public was able to make and use the invention.

Now, the written description is the second part of Section 112 and according to the Supreme Court that provision was there to take away from the inventor the means of practicing upon the credulity and fears of other persons by pretending that his invention was more than it really is or different from its objects and that the patentee was therefore required to furnish the invention in the specification.

In other words, the standard for written description would be whether one skilled in that technology reading the specification would recognize that the inventor had possession of the claimed invention. And possession is not a suggestion that he had to have performed it. It is a fuzzier term which the courts have not really articulated too clearly.

Now, according to the Federal Circuit the purpose of the written description requirement is broader than

merely to explain how to make and use. The applicant must also convey with reasonable clarity to those skilled in the art that as of the filing date he or she was in possession of the invention. And the invention is, for the purpose of the written description, whatever is claimed.

Throughout most of the patent system this was a question of whether or not new matter crept into the application so that the applicant would file a specification, the examiner would make some rejection and then an amendment would come in. Often the amendment would add new information, information that wasn't clearly there in the first filing. Well, the patent examiner doesn't always catch that and frequently these things will then publish or not publish but be granted and there's a question as to whether or not there is support in the original application for that newly added information.

Now, this information can come in either explicitly where somebody adds a new limitation such as putting in that a particular process can be most suitably used at a higher pH or it can come in implicitly where someone removes a limitation.

In Tronzo v Biomet, which was 156 F.3d 1154, the

Federal Circuit looked at a particular medical device and when the applicant had originally filed that medical device one part of it required a conical structure.

Through the long process of prosecution, that conical structure seemed to be deleted from the claims and it therefore could be used by or could be practiced by something that was cylindrical or slightly spherical. The Federal Circuit recognized that adding information could come by removing a limitation that was there in the original filing. And they found that it was not enabled.

Recently, at least in biotechnology, the Federal Circuit has looked more towards the quality of the description, that is, is the information that you have used to describe it sufficient.

Now, in molecular biology you can often give a name to something long before you actually have possession of it, long before you actually have it in your hand. You can give it a name. You can tell how you would go about obtaining it and at the same time you don't really have it yet you're just indicating how one would get it if they wanted it.

Well, that goes to enabling, being able to get it. It doesn't go to whether or not you described it. In the case of the Regents of the University of California v. Eli Lilly, the Federal Circuit pointed out

that the name cDNA, which is a biotechnology term, is not itself a written description of that DNA. It conveys no distinguishing information concerning its identity.

While the example provides a process for obtaining the human insulin coding, cDNA there's no further information in the patent pertaining to that cDNA's relevant structure or physical characteristics. In other words, it doesn't describe the insulin cDNA.

According to the court, cDNA is not defined by describing the mere name even if it's accompanied by a way to obtain that protein and a name of what that DNA would encode for.

That caused quite a stir in the Patent and Trademark Office and required the Office to go through a good deal of training of the examiners, retraining of the examiners along with putting out a set of guidelines so that the outside world would see how these examiners were being trained.

MS. MICHEL: Scott?

DR. CHAMBERS: Yes.

MS. MICHEL: Could you give an example from that case of the relationships between rats, mammals and humans?

DR. CHAMBERS: Yeah, I can. And I'll do it right now. When you file an application, many times what you

want to do is you want to have a broad scope so that you can not only practice your invention but you can also keep people a good distance away.

In molecular biology you can often use a model system to get the first part of an invention. You can use a model system to get the gene of, say, rat and the beauty of molecular biology is that you can then use that rat gene to get all sorts of other genes that are the same in different species.

Generally speaking, when someone files an application they may have had the sequence for one of the model systems, mice or rat, and then they would claim that particular gene in other systems such as humans or in all mammals, or all vertebrates.

The question that was before the court in the Regents of the University of California is, can you get that broad claim when all you've given is a single or one or two types of species rather than the broad genus.

It's certainly true that generally if you have one gene from one organism you can use very common methods to get the genes for any other organism that you would identify that would be that same gene.

But the Federal Circuit decided that you do not get a sufficient written description providing a single species to cover a broad genus.

According to the court, a description of a genus of cDNA's, which we can think of generally as genes, may be achieved by means of a recitation of a representative number of cDNA's defined by a sequence falling within the scope of the genus or a recitation of some structural feature common to the members of the genus which features constitute a substantial portion of the genus.

So the Federal Circuit indicated that they wanted a good deal more than a single representative in order to get a broadened claim to an entire genus that is very important in this field since you're in a race, usually with other laboratories, to get patent protection.

And you may well be able to get patent protection for the first organism that you have isolated, that is, for the cDNA from rat but the real interest is getting it for a broader genus, one that would include humans.

And consequently, this caused quite a stir as people came to grips with the idea that written description could mean more than just adding information but actually went to the quality of the information that you were provided.

MR. COHEN: Before you move off that, you talked about a representative number.

DR. CHAMBERS: Yes.

MR. COHEN: Is that a concept that's flexible,

that varies from one setting to another?

DR. CHAMBERS: You bet it does. I would say it varies from one examiner to another. It is going to depend on whether or not one of skill in the art would believe that you had possession of that genus when you had five examples, ten examples, something like that. And the examiner typically will have some background understanding of the technology and he will be the fact finder in that situation.

MS. MICHEL: If I recall the case right, is the concept here that if I have the DNA for rat insulin, can I claim DNA for mammal insulin and thereby have property rights over the DNA for human insulin.

DR. CHAMBERS: It seems from that case that you can't. Mammalian insulin gene would be a broad generic covering. It would cover all the mammals that have insulin and would cover their genes.

And if you have a single representative such as rat insulin you would have difficulty in showing that that was a sufficient representative of the entire genus. It's possible that your specification along with a single species could describe a whole genus. That possibility would occur if you could show that I have looked at ten different species. They all have exactly the same sequence. Let me have the claim to cover a whole genus.

That may well be possible. But it is unlikely that that would be the situation.

Usually you have to have more than one but that's something that the court is still struggling with. There have not been a lot of cases from the Federal Circuit on this. There was a case in 1991 which was an interference case, and I'll mention interference hopefully later on, but it's a priority dispute and it dealt peripherally with this issue. And then the regents came across in 1997 and we have not seen the Federal Circuit speak on this precise issue since then.

The third requirement of Section 112 is that the applicant provide the best mode. Now, it's not really the best mode of practicing the invention. What it is is the best mode that the applicant knew at the time he filed the invention. So it's a two-pronged inquiry.

First, you have to ask did the inventor have what he or she considered to be the best mode when the application was filed. And two, did the specification set forth that best mode?

It's a subjective requirement in other words. You have to look for what the inventor knew. There are situations where companies will frequently have certain individuals dealing with the initial discovery. You get some economies of scale having a research scientist only

do research and then other portions of the company deal with enlarging the scope of that particular process so that it can be used industrially.

In situations where they take it from the researcher when it's first discovered and send it over to another area of the company for scaling up, when the scaling up operation comes across better ways to do things those don't have to be in that initial application as long as the inventor didn't know about them.

Now, best mode when it comes into the Patent Office is also something that's presumed to be satisfied. The examiner seldom if ever raises the issue that the applicant has not provided the best mode in the application.

I think I'll explain patents a little bit by showing one. This is one of the first patents that came out that set the stage for molecular biology. It's the Stanley Cohen/Herb Boyer patent which talked about and described and disclosed flipping out pieces from the DNA of one organism and putting it into another organism.

You can see that it has a particular date that it's issued. It's got an indication of related patent information right here and then it talks about what information was disclosed to the examiner by the applicant and what information the examiner turned up

when he was looking for information in this particular area. It also tells who examined it as well as the outside lawyer.

At the end of that first page there are a number of numbered columns which are known as the specification or the disclosure and they end with numbered claims which are single sentences describing what the inventor believes that he has invented.

In this particular case what Cohen and Boyer thought they invented was a compilation of matter which in this case was a biologically active molecule that was made by taking a piece of nucleic acid from one organism and putting it into another organism.

MR. COHEN: Sometimes we hear about claims; sometimes we hear talk about claim elements. Sometimes we hear talk about limitations. Could you point in here to --

DR. CHAMBERS: Okay. I can point to -- that's actually going to be something that would depend on the particular judge. And that would be quite an important aspect of dispute in a litigation. But this would be Claim Number 1.

Usually this first part of the claim is not considered to have an effect on the scope of the invention but sometimes can. And then, there would be a

claim element in this particular one, it would be a first DNA segment containing an intact replicon. So you could consider that to be a claim element.

You could also consider it to be an intact replicon recognized by the cell. You could extend the limitation to have a lot of sublimitations or you can just roll them all into one. I mean, it's not something that is easily explained because you can be sure that people will differ greatly.

And they'll differ on this particular issue because claim limitations or claim elements can have an effect on the scope. When we hear about the doctrine of equivalents I think we will hear a little bit about narrowing that occurs during prosecution.

And the narrowing can often occur in terms of a claim element. Well, if you're the patent holder you want that element to be as small as possible because that's what's going to have been narrowed. If you're an accused infringer, you want it to be as large as possible because that will suggest that that shouldn't be enlarged. Does that answer it?

Here are just a few other patents. This one is to a stem cell patent, pretty much a similar set-up. What you have in some patents are drawings or figures that will help to explain the invention.

Here is a particular drawing showing stem cells for some particular primate, certainly not humans. And then it ends with a number of claims also where it's claiming a purified preparation and then it uses such terms as "capable of" which is a functional way to claim your invention rather than just claiming it structurally.

MS. MICHEL: Scott, I think that that patent is an interesting example of the genus-species issues you were talking about before in that the work there was done with monkeys.

They're claiming primates, and I suspect there will someday be litigation on whether primates can encompass humans and that will bring up some of those written description and enablement issues that you were talking about before.

DR. CHAMBERS: Yeah. I don't think that there will be a discussion as to whether the primate would cover humans in that particular sense, but whether or not there would be a question of does the patent system cover humans. But it is definitely also true that if they only gave a single example of a primate that was a stem cell it might be different to have a broad claim like this.

I think in this particular patent they had a number of different types of primates. And you have to appreciate the fact that enablement would go to whether

it required undue experimentation to get the human form.

And so from the enablement standpoint in this area a year or two would not be undue experimentation. So it may well cover from an enablement standpoint.

For written description, as I have said, it's hard to say how the courts are going to look at those things in terms of the breadth that they're going to be permitting.

Here's the patent on the first transgenic animal. It was a small mouse. The figures in this particular patent show the way the nucleic acid was constructed to put it together.

Often the description of the invention will have tables that have definitions as well as describing how to make and use the invention. And once again it ends with claims that point out particularly what the applicant felt was his invention.

And this final one is the patent for the polymerase chain reaction which ended up getting the Nobel prize for the inventor. It's a very important patent and there's always questions in the patent system whether or not certain things would have been disclosed.

I mean, there are two ways to protect your information. One is through patents and another one is through trade secrets. And certainly you are less likely

to be forthcoming with all the information if you are not permitted to protect it with a patent.

And you're less likely to be forthcoming with information if you are not required by the patent system to provide the best mode that you know how to make and use the invention.

Now, they don't all start out this way as a patent like this. They start out by a filing of a number of pages in the Patent Office and they can come in in two different ways to the Patent Office, either as a provisional application, which is only a specification naming one or more inventors. That is just a placeholder.

It is not examined but it is there to permit an individual to have basically up to a 21-year term from the priority date that he claims. It is also a way to allow people to file very quickly. Within a year of that provisional application, or initially if that is your choice, you file what is known as a nonprovisional application. And that has a specification. It names the inventors that are known and it ends with one or more claims.

That particular type of an application, a nonprovisional, is examined for patentability and it's going to go to one of 3,000 different patent examiners.

Now, when it's filed it first goes to the Office of Initial Patent Examination. What they're going to do is basically look to see that all the forms are signed and to make sure that there is a fee that has been paid because that's very important in a user-funded organization.

And then it's going to go to one of seven technical groups. There are two chemical groups, three electrical groups and two mechanical groups. Now there's a lot of overlap in these particular areas and you can see growth in the particular technology centers.

For example, at one point in the '80s it was clear that hardware, which is the hard wiring for electronics, could be implemented just as easily with software. For that reason, you had to have a patent that would cover both hardware and software in order to have any effective protection.

That meant that people were starting to file applications which held both and eventually applications which simply held software. The software examination for that reason goes into the electrical group because it was a natural flow of that information.

As that developed people started simply filing software patents not worrying about the hard wiring and as the software became more sophisticated it began to

take on the structure or the feel of basically a business method. So those business methods are also shoved into the computer section, the electrical section.

In contrast, searching large numbers of nucleic acids started out in the chemical section and while that now has a good deal of computer hardware and computer software involved, that also still goes to the biotech section.

So you can have different sections even though they have a name that sounds like they're doing one type of work, they're actually doing another type of work.

Now, each of these tech centers has about 400 different examiners and the tech centers are broken down further into workgroups. Here is the tech center that would deal with biotechnology inventions. And each of these workgroups covers a particular generalized area.

And within these workgroups then are art units and they're headed by a supervisory patent examiner, or an SPE, and he will deal with about 16 to 25 different examiners.

Now, they handle at these tech centers about 300,000 applications a year. They issue about 160,000 patents a year. Now, the growth rate for filing is roughly ten percent. It's a little higher than ten percent in that particular technology sector that I just

showed you but in some areas like business methods the rate of filing can be upwards of 20 percent as people start to engage in making sure that they have protection in these particular areas.

Now, the examiner is most often trained in the same technology that he is examining but only a very small percentage of those examiners, are actually lawyers.

At one time the Patent Office had a large percentage of lawyers but the market forces ended up pulling most of those out of the government and into the private sector. So now there's roughly five percent of the personnel at the Patent Office being lawyers and those are concentrated in areas such as the solicitor's office or special programs not in the examining board.

The patent examination in the United States is purely ex parte, that is, the examiner is the fact finder and the only individual presenting information for the examiner is the actual patent applicant.

The examiner is going to read and review the application which can sometimes be several hundred pages. They can do the search for the prior art to find what is in the prior art. They then write it up.

They read and review the applicant's response when that comes in and then they draft a response and

there can also be interviews that occur. And finally they will either issue a patent or they will prepare the examination for the Board of Appeals, writing an appeal to the Board of Appeals which is an internal agency fact finder.

This is done in a relatively short time. When I was an examiner the highest amount of time that you could get for this process was 24.9 hours. And many of the examiners were working at less than half of this in order to do this entire process.

So examiners tend to be able to look at this stuff very quickly and at the same time when you see a list on the patent of 20 or 30 references you have to appreciate that the examiner probably reviewed those but maybe didn't give them a thorough review.

The case law as well as the statute indicates that the applicant is entitled to a patent unless, so it's the examiner's burden to show that there's a lack of utility or that there is obviousness to the patent or that it is anticipated or not enabled or lacks written description.

The Patent Office doesn't have any laboratories or testing facilities. It's got to be what is found in the prior art. The examiner in order to make the rejection has to find that more likely than not the

application suffers from a lack of utility, that it is obvious or that it was anticipated or lacked enablement.

When the examiner makes a rejection the applicant can then come in and he can amend the application. He can also file continuations, which are just further prosecution of that particular application.

The United States differs from its trading partners in one respect in the patent system, in a number of respects, but one important respect and that is in the duty of disclosure. It's a duty of candor. In the foreign systems the applicant does not provide any information that he has or does not have to provide it. However, the foreign systems allow for interparty discussions of the application as it's moving down toward the issuing process.

In the United States that is generally kept hidden but the applicant is required to come forth with any information that the applicant feels would be material to the patentability of the invention.

It's material if it establishes a prima facie case of unpatentability or it's material if it indicates a different position than the applicant is arguing before the Office in an argument suggesting patentability.

The duty of candor applies not only to the inventor but also to any attorneys involved. Any

individual that deals with that particular case has to come forth with this information if it's available to that person or they know about it.

And if they don't and they have not provided that information with an intent to deceive the Patent and Trademark Office, it can end up rendering the patent application or the patent grant invalid.

Generally speaking, the Patent and Trademark Office does not raise issues of the duty of disclosure. In the 1980s the agency was investigating a good number of questions of failure of duty of candor and it was taking up too much time and resources and so they determined that they would just let the courts do this. And so the Patent and Trademark Office no longer investigates the applicants or no longer investigates cases for lack of duty of candor.

If the examiner feels as though the application as claimed or the invention as claimed is not patentable, he will continue to make rejections and the applicant then can go to a higher authority, which is the Board of Patent Appeals and Interferences.

The board is composed of a number of individuals who have trained in the technology, have a law degree and have been, generally speaking, patent examiners at one point. They will meet in three-member boards and they

will look over rejections to determine whether or not it was appropriately rejected or not.

If they determine that it was inappropriately rejected, it will generally be sent back to the examiner and it will be issued very quickly. If the board determines that it should not issue because it's not satisfying one of the statutory requirements, you can appeal that decision either to district court or to the Federal Circuit.

If you appeal to the district court you're allowed to put in additional information, additional evidence. If you go to the Federal Circuit, it's like any other agency action where the appeal is on the record that was before the agency and the Federal Circuit will not do fact finding.

It is possible, once the patent issues, that additional information will come out in the form of printed publications or patents that suggest that perhaps the patent was not valid.

The patent owner or third parties or even the Commissioner of Patents can request a reexamination of that patent. That reexamination only addresses Sections 102 and 103 which Jay spoke about. It doesn't address enablement or written description or utility. And it's a very limited type of examination because it's only on

printed publications.

Now, according to the Patent and Trademark Office, it is printed publications that were actually not used by the examiner in the first examination. Other authorities suggest that it is in written publications that were on anything that was not in the original patent filing. As you recall, when I showed you the patent there were a list of different references that were provided in each of the applications.

There's a question as to whether or not you can have a reexamination on particular patents that are in that list or not. But suffice it to say that it is a limited-type of reexamination of the patent just on new printed publications and it's just for compliance with 102 and 103.

Now, there is recently passed legislation that allows interparty involvement in the reexamination process. Since a third party can start the reexamination process it seems only fair that that third party should be allowed to participate. And this third party reexamination would permit that up to a point.

They can participate and file briefs with the agency up until the time that a determination at Board of Appeals level is made. At that point they are no longer allowed by right to put any information into the case and

they are also precluded by making certain challenges in district court on those issues that they raise.

So many people feel like the third-party reexamination is too limited because you don't really get your day in court in front of an Article 3 judge, whereas the old ex parte reexamination allowed you to step into district court if necessary at a later point and see if the patent really was valid.

MS. MICHEL: Scott, if the third-party requester disagrees with the board's decision, is there any ability to go to the Federal Circuit?

DR. CHAMBERS: There is not. There is not by his choice. He has no right to go to the Federal Circuit. If the board was sending it to the Federal Circuit, he would have the opportunity to file an amicus brief in support of the board if the Federal Circuit would permit it. But if the board determines that the invention is patentable on the record, that's the end of it and he is not even allowed to challenge that in district court in many cases.

There is another procedure that can affect the scope of patents and that is reissue. Very early in the history of patents the courts determined that the Patent Office could reissue patents. And that eventually became codified and now there's a section of the Patent Act that

allows reissuing of patents. If they are wholly or partially inoperative or invalid, the applicant himself can request that the patent be put before the agency again.

The reissue can enlarge the scope of the claims if it's filed within two years. However, if it's filed after two years, all it can do is fix mistakes that are in the claims.

Finally, I want to conclude with talking about the interference procedure. Under the United States law, as Jay indicated, the patent is given to an individual that is the first to invent not necessarily the first to file.

When there is a dispute, a priority dispute as to who was the first to invent, if the dispute occurs in the agency it goes into an interference procedure. And that agency determination requires that one of the applicants for the patent show that he was the first to invent the particular invention that is being claimed.

Now, if there is an agreement between the two parties to settle that interference, that agreement has to be filed with the Patent and Trademark Office, so there is a more limited opportunity for individuals to collude as to whether or not they should have particular rights.

But from the standpoint of international practice, it's quite unusual having this system because other places, other trading partners that we have, have a first-to-file system where they don't have to worry about whether or not someone was the first person to invent an application and just didn't file for several months or several years.

What should be kept in mind, however, in terms of the interference procedure is that it permits an extension of the patent term beyond the 20 years. Under certain situations the patent term can be extended for the time that was spent in the interference procedure and for that reason it should be kept in mind as a potential way to extend the term of the patent. Thank you.

MR. COHEN: I have a few follow-up questions. Some of them will take you back to your time working on the utility guidelines and description guidelines. I'm really interested in trying to flesh out just a little bit more, where there are presumptions, what an examiner has to do to establish a prima facie case challenging something, questioning something.

Let's try utility first. We know that there's a credibility standard there. What if an applicant comes in and presents facts showing that the use that he has identified is plausible? You don't know if it's really

true, if it's correct but I guess somebody with ordinary skill in the art would regard it at least as plausible. Is that where things stop?

DR. CHAMBERS: I would say it stops right there. It's always the examiner's burden but keep in mind that something else will take effect at that point. Okay. They have crossed the barrier for utility. Yes, it seems plausible. I'm not going to laugh about it. But is it enabled? Now, you're still going to have to, as an examiner, show that more likely than not that at some portion of the claim it's not enabled. But often enablement is easier because you can describe why one of skill in the art would think that this would not really work that way.

It can be a difficult situation but it depends on the examiner. Some of them are creative at finding out simple ways to explain it but it can come down to simply a well-reasoned argument and that is sufficient. But just getting through utility on that credibility standard is still going to leave you open to a challenge on enablement or lack of enablement.

MR. COHEN: Another aspect is the written description. And in just looking through the description guidelines, I saw a reference to the fact that there's a strong presumption that an adequate written description

of the claimed invention is present in the specification as filed. Could you put this in context and discuss it a little bit?

DR. CHAMBERS: There's a strong presumption that when it comes in it's got a written description. But remember we were talking about two forms of written description. One, the newly added information and the other one is this idea of the sufficiency of disclosure.

Now, for the newly added information the examiner is in a pretty good position if he just says, look, I looked through the application. I see no reference to combining pH 9 with this particular invention.

Well, that in itself would make the applicant have to show one of two things: first, page and line where it is actually there, or come in with some reason that someone of skill in the art would know that it was there.

For example, they might have been using a particular marker like phenolphthalein that turns a particular color at pH 9. And they might have said in one of the examples, it turns this color. They come in with a declaration from one of skill in chemistry saying I'm one of skill in chemistry. I know when I see this color change it's a pH 9. Okay. That's sufficient to show that you really had that idea at the time.

Now, for the other one, for the question of sufficiency, that's going to be a little more difficult. If the applicant comes in and has a declaration saying, not from the inventor but usually some other party, I'm one of ordinary skill. I would know when I read this immediately that the applicant had possession of this.

Well, that can be enough to show that they had this written description in the sufficiency sense and the examiner can either provide a declaration of his own or a reason why that declaration was insufficient. Perhaps the expert didn't say exactly what needed to be said. But if he can't come up with one of those reasons, it will issue.

During litigation, of course, you can imagine that will be heavily challenged. But from the standpoint of can I get that piece of paper that allows me to walk into court, yeah. You can get an expert to say.

MR. COHEN: I guess the last thing I'd focus you on is nonobviousness. If an examiner is questioning whether something is nonobvious, describe what he would need to establish.

DR. CHAMBERS: He would need to establish that the limitations in the claimed invention were somehow in the prior art in more than one form, even if it was in a single reference but in different parts, and then that

there would be a motivation to make that change.

For example, say the invention is an aluminum gear that is a certain size. The examiner finds that same type of gear in steel. He finds a reference that says aluminum can sometimes be used in place of steel if you don't need the strength.

Well, there is not only motivation to make the gear -- at that point you would still have to have a motivation and you would come across with a motivation such as one would want to make this gear out of aluminum so it wouldn't rust. It doesn't have to be a sophisticated type of motivation but it has to be some reasoning that somebody would make that kind of combination.

But from the standpoint of obviousness that's usually what the argument is about. In the Patent Office, the examiner is going to conclude that just about everything is obvious and the applicant is going to conclude that just about everything isn't.

And the examiner's job is to put it into clear enough terms that it's understandable. There will be a certain amount of fact-finding required looking at the reference. The case law holds that what a reference teaches one of skill in the art is a question of fact. Well, those facts are going to be determined by the

examiner, by the Board of Appeals, and then they're going to be reviewed at the Federal Circuit.

MS. MICHEL: Do you have any sense of how common it is for an examiner to make a written description or enablement rejection as compared to say obviousness rejections?

DR. CHAMBERS: In certain fields it is unheard of for the sufficiency of written description. Now, the written description when an amendment comes in and you can't find where this particular widget was described in the original application, that just depends on the particular field.

But for the sufficiency written description there is not much of that going on in the mechanical arts, not much of that going on in the strictly chemical arts or even in the software area. But there is quite a lot of it at least initially raised in the biotech area.

I mean, if it's raised and the applicant explains why one would think, one of skill would think they were in possession, that might be sufficient. I think that the claims are a bit narrower now that are being issued than before Eli Lilly. But I would expect that a patent attorney that did not file asking for the broad claims was letting the client down.

MR. COHEN: Before we go to break one more area

that maybe you could help discuss a little bit. You talked a bit about amendments. We also hear talk about continuations. Could you lay out some of the distinctions there and maybe try to put it in a context of a situation where perhaps a patent applicant is aware that there have been other developments in its industry, perhaps by competitors and may somehow be trying to take account of this over time? I asked a couple of things --

DR. CHAMBERS: Well, yeah.

MR. COHEN: And ran them together.

DR. CHAMBERS: When you file the application you're allowed by right two chances to get the application allowed. You will file that initial filing. The examiner will often say, no, these claims do not satisfy the statute. You can make an amendment and then you send that back to the examiner.

The examiner, if he still feels that the claims don't satisfy the statute, he will, generally speaking, make the action final. You no longer have a right to put an amendment in.

At that point you can provide an amendment and if the examiner wants to let it in, he will. If he doesn't want to let it in because it raises new issues, he simply won't do it. At that point you can file a continuation. That gives you two more bites at the apple, two more

chances to get your claim allowed.

There is also something called, under the U.S. system, a continuation in part. That means part of the material is a continuation and part of the material is new information, new matter.

The new matter information will get the priority date of the continuation in part, when it was filed. The old information will get the priority date of the original filing.

Now, that means you will have claims that go to either the old date or the new date and sometimes when people want to bring in information they will file a continuation in part; they will put in these new concepts that perhaps the industry is dealing with; and then those are in the continuation in part.

An examiner looking at that can readily determine if that idea was in the original application. He can determine what the date was. If there are intervening references so that the first application was filed in 1990, the continuation in part, or CIP as it's often called, was filed in 1992, if he finds something in that interim he has no qualms about making the rejection based on that intervening prior art and simply saying your date for this concept is 1992.

MR. COHEN: I was just going to say I think you

directly answered what I was getting at and I'm looking forward to reading the transcript so that I can understand how you answered it.

MS. MICHEL: Let me follow up on a point there though. If you could explain a little bit about the concepts of applying for continuation applications even though the examiner has allowed the patent. Say the purpose of a continuation is not another bite at the apple but to word your claims in a different way.

DR. CHAMBERS: Well, keep in mind that if you're going to word your claims in a different way that it would be new matter unless that idea was in the original filing. So, yes, you can make that filing. But is that justifiable? You had the idea; you just didn't have it worded quite the same way.

Now, there are other reasons for continuations other than the one that you suggest. You might have a situation where the patent examiner is not willing to let you have a broad claim but he will let you have a narrow claim. You need that narrow claim to show your investors, look, I have some patent protection.

So I get that and I keep asking for the big claim. Or maybe I can show commercial success or something like that which is a difficult thing to show at the Patent Office. But there are very good reasons to

file these continuations even when you have already gotten an issued patent.

MR. COHEN: I think we'll take another ten-minute break. I'll point out for those of you who haven't discovered it, we've been trying to keep copies of these slides out on the table in front so you can pick up your copies.

(Whereupon, a short recess was taken.)

MR. COHEN: We can move on to our final lecturer today. That's Lawrence Sung, an Assistant Professor of Law at the University of Maryland School of Law. He has taught at the George Washington University Law School and American University, Washington College of Law and the Northwestern School of Law, Lewis and Clark College.

In private practice he specialized in biotechnology patent litigation at Foley and Lardner, then Arter and Hadden, and later McKenna and Cuneo.

Recently, he has served as lead counsel for the American Intellectual Property Law Association, amicus in support of petitioner in the Festo litigation in which the Supreme Court heard oral arguments just last month.

Professor Sung has published extensively on intellectual property issues including those concerning biotechnology and technology transfer. Among his many

accomplishments he holds a Ph.D. in microbiology.

So I'm going to turn the lectern over to Professor Sung. He'll be talking to us about the remaining topics for today including infringement and doctrine of equivalents.

DR. SUNG: Good morning everyone, and I want to thank Bill for his kind introduction also the invitation to be here with you this morning.

We are in the home stretch of our morning program and rest assured that I like some of you are sort of a noontime lunch person. So if you're thinking about lunch at this point in time, I'm right there with you.

What I wanted to do is to get an opportunity to speak with you about the scope and enforcement of patent rights. And essentially this seems like a fairly straightforward proposition and one of the things when Bill had invited me to come speak here today, when he mentioned who else would be on the panel, having worked with both Jay and Scott many years ago, I certainly know what a tough act they are to follow.

But I took some comfort in that they would set up an excellent foundation for where we're going to be going from here in talking about the scope and enforcement.

Perhaps one way of getting into it is to ask initially what's the real problem here. Why is this such

a complicated area and why is it so important that we understand the nuances about how this is done?

And perhaps it will be easier for us to approach this if we think about how this would impact us in sort of a real world situation.

My wife and I recently moved back to the Washington area after spending two lovely years in the Pacific Northwest enjoying ourselves while I was teaching out at Lewis and Clark.

And when we came back here we bought a home and moved into a new development that was under construction, houses still going up. And one of the things that we received after paying a large sum of money or, more correctly, entering into a great amount of debt was a nice little plat to go along with our deed. It basically had a survey with all the markers where your property lines were and such.

And I remember one day my wife came up to me and said, so which one of those trees out there are ours? What's on our property? And I looked at her and it was a long day but I just shrugged and said, you know, I really don't know.

She said, wait a second. You've gone to school all this time. You can read this and I looked at it and turned it around and said, you know, I really think we

need an expert for this, honey. Let's go ahead and get a surveyor. Do you know any? No, not particularly but let's open up the Yellow Pages. Let's get somebody who really knows what they are doing.

So a team arrived very early in the morning with all their equipment, went out there onto the property, staked out a whole bunch of different things. They came back to talk to me and I said, well, what can you tell me?

And they said, well, your property line is 25 West 32 North. And I thought, hmm. That makes sense. But is that tree over there on my property or not? And that was the simple question I had for them.

And he was able to provide me with a very clear answer because he had been able to go to a central repository from the state and basically pull this plat using the proper equipment and his expertise and be able to tell me that tree was indeed on my property and I could walk away extremely satisfied, notwithstanding the $700 fee I had to pay him for that particular expertise.

But yet I knew and that's a very valuable component to this entire conversation that we'll be having for the rest of the morning.

What's the difference with that and intellectual property rights particularly in the patent area is that

although we have a centralized repository from everything you have already heard in terms of our morning's discussion, there's a question that's involved.

There are actually more than one question that's involved. And the question is where are those property lines? Is this, in fact, as established what you ultimately get in a real property sense with your deed?

Can we hire somebody to come and take a look, looking at that deed and be able to tell you is this within your patent right or is it without your patent right?

So let's go through and compare some of that. Number one, somebody could come out, probably for a little bit more expensively than $700, and say well, I'm pretty sure but don't quote me that this is within your patent right.

Well, why aren't you sure? I thought this is what you did for a living. Well, it's because no one's really quite sure. We have to interpret where that line is. The line is not necessarily where it's drawn. It could be a little bit to the right. It could be a little to the left. There's a difficulty in here.

And again, don't hold us to that particular comment because we're doing the best we can under the circumstances because there is no set property boundary

here.

And everything that we'll see today in terms of how the property boundaries are interpreted lend to that difficulty.

Well, there's a corollary problem with all this, not just is there an uncertainty with knowing where your property lies with regard to your patent rights but there's a process problem.

And another anecdote that I'll give you very quickly is to talk about a movie that I saw, well, it's go to be ten years now, where there's a young set of interns walking around on grand rounds and sort of going from patient to patient as they commonly do. And they walk up to one patient and the attending physician says, okay, tell me what you think the problem is with this patient.

And the patient is sitting there very casually or actually more intently listening to what all this is going to be. The intern responds and says, he has a very rare metabolic disorder that he ultimately obtained while he was on safari in Africa. And the attending physician with a bemused look looks at the intern and says, how can you tell? That's fascinating. That's amazing that you were able to come to that conclusion.

And the patient is still sitting there looking

and the intern looks back and responds and says, well, frankly, I don't know. You don't know. None of us will know. We won't know until the autopsy. Well, you can imagine that the patient is not too happy to hear about that being the process either.

But that's essentially what we have in the patent area simply because you don't know until you go through the process of litigation what your ultimate patent rights were.

The interpretation of your property is not done until that time point and certainly the resolution and the arbitration of all that is not done until the very end.

It may be very dissatisfying for people to know that. It certainly causes a lot of difficulty in terms of business planning and the predictability is certainly not there and is why there is a lot of criticism about the patent system the way it's set up.

But one of the things that was introduced earlier on was to say, well, as a matter of public policy the way the U.S. patent system is set up, we don't devote an extraordinary amount of taxpayer dollars to the perfect examination process.

Indeed in Europe it gives you an opportunity to have certain pre-grant opposition procedures and perhaps

a little bit more refinement in terms of whether something is truly patentable or not.

Here in the United States we have a set amount of money that's devoted but also, as Dr. Chambers talked about, a set amount of time, let's say, ten hours, whether it's a concrete block or cold fusion.

Well, if you're a physicist maybe that's the same thing but for most people they're dramatically different types of technologies. How can we look at them so fungibly for something as important as the examination process because ultimately once they are issued they do have the presumption of validity.

They will incur transactional costs because of their placement out there in the public. They're a notice to the rest of us, wait a second. Somebody has sought patent protection in this area and this is preliminarily what they think they have or what they claim.

Let's talk a little bit about some of our discussions for today. We're going to get into the concepts of infringement and perhaps what will help clarify what infringing conduct is is to talk a little bit about what the defenses to infringement are under the patent laws.

And more importantly with that type of

enforcement what are the penalties that are involved? What are the remedies that we possibly have in this area? And hopefully, you will be able to draw some analogies to practice areas that you are more familiar with as well.

Again, I have an easier task that doesn't require us to get into, indeed, all of the intricacies about the patent law but we can look at them and analogize them to other areas of litigation and practice generally.

Now, let's talk about the cast of characters that are involved here. First of all, one notable absence is going to be the Patent Office. As Professor Thomas had mentioned the Patent Office doesn't quite have a role here in terms of the enforcement. And even where it focuses on the scope issue and what the patent rights are, it's done that as a consequence of the examination process, not so much as defining easily for us what the actual legal scope is going to be. That's left to the federal judiciary.

Now, there's no analogous criminal prosecution capability under the patent laws. This is all based on civil litigation, civil remedies. But at the trial level you have the U.S. district courts across the country and, indeed, in addition to that we have the Court of Federal Claims which is responsible for certain actions known as 1498 actions against the U.S. government for patent

infringement.

Another venue at the trial level can be the International Trade Commission. There are statutes that authorize the International Trade Commission to determine whether or not particular goods coming into the country would infringe a U.S. patent.

And if, indeed, they are held to be infringing, the ITC may issue an order to the Customs Service to impound and stop importation of those particular goods. And in that sense it allows us, even though U.S. patents are territorially limited in authority, almost to reach beyond our borders. These are in rem actions but in that capacity we are essentially asserting U.S. patent rights over those which may not otherwise be subject to our personal jurisdiction.

MS. MICHEL: Lawrence, let me ask one question. Am I remembering correctly that there's no damages available at the ITC? It's just injunctive relief.

DR. SUNG: That's right. In terms of the injunctive relief there is an analogy to a preliminary injunction in interparties matters. The ITC will issue something known as an exclusion order to the Customs. And essentially that stops the importation. That's correct.

Once any of these determinations are made at the

trial level they can proceed up to appeal. And as Professor Thomas had laid out for you in terms of the Court of Appeals for the Federal Circuit, they have exclusive appellate jurisdiction regardless of where they come from.

And in that way there is a lot of strength in terms of looking at a consolidated consistent fashion of considering these types of issues on appeal. The difficulty as Professor Thomas also alluded to is that there isn't as much of a rich body of dissension and diversity, let's say, as a result of having the authority of exclusive appellate jurisdiction vested in one court.

As a result of this although there can be an appeal to the Supreme Court often times there aren't. And one of the things that many commentators have talked about is that normally what the Supreme Court, as many of you are aware, there can be intercircuit conflicts that need to be resolved by the high court.

Well, when you're talking about patent related issues they have already been consolidated into an exclusive appellate authority. And for that reason there is no intercircuit conflict that we can look at.

And perhaps the only analogy that exists is looking at perhaps dissents and concurrences and other types of opinions expressed through the Federal Circuit

panel, either in the three-judge form or in an en banc review.

Now, in terms of infringement, let's look at this briefly from an infringement conduct and infringement standard dichotomy.

One is that we'll talk about what types of activities a business or individual could engage in that would subject them to the infringement statutes and then talk about what the tests for infringement actually are.

Now, the various types of conducts that are covered by statute include direct infringement, vicarious infringement and my loose miscellaneous category, other infringement.

And as was discussed earlier the patent statutes ostensibly are in primary form from the 1952 Act, certainly at a time that many of the issues that we are now discussing were not even contemplated. As a result of certain amendments the other infringement category is simply a matter of tacking on additional statutorily prescribed activities to all of that.

Now, in terms of direct infringement you have heard a little bit about this from the introductory speeches. They do cover a fairly wide range of activities. They are meant to be broadly encompassing. We can look at manufacture, use, sale as the primary

examples and then more recently in terms of statutory amendments the offer to sell as well as the importation may be covered under the patent laws as direct infringement also.

Now, you can well imagine that the increase in terms of looking at importation and particularly offer to sell broaden the scope not just the types of activity but also the temporal nature of that activity.

Certainly, things that folks may have originally looked at and said well, this type of business activity isn't really a sale and, in fact, may arguably be even an offer to sell. It reaches very early on in terms of business activities and conduct that could be encompassed.

Of note, what I would just like to add is that the concept of use is ill-defined. Many things can fall under that category. With sale and offer to sell it does not have to comport necessarily with other definitions under the law of what a sale or offer to sell is. It certainly does not have to comport with UCC requirements for those purposes but may more broadly reach in that sense.

Now, in addition to direct infringement which would be you are practicing this claimed invention, everything that the claim specifies. If you have A, B

and C, in fact you are doing A, B and C and are a direct infringer. That isn't the end of the liability spectrum that we can look at. We can look at vicarious infringement as well.

Let's say, for example, in that hypothetical where the patent claim specifies you must have A, B and C. I as the consumer am putting together A, B and C. I am a direct infringer. However, somebody who is supplying one of those ingredients or components to me, somebody who is giving me the C would not be a direct infringer because they are not practicing every element or limitation of that patent claim.

However, by directing C to me purposefully they may be a vicarious infringer through a variety of statutes either inducing infringement or contributory infringement.

And although there is sometimes a little bit of a fuzziness in the courts about what constitutes inducing infringement versus contributory infringement, understand they're certainly broadly encompassing enough to look at this type of supplier relationship or in some other circumstances where the patent claim itself is to a process, for example, the treatment of a particular medical symptom.

Well, who would be infringing that? Again, the

physicians would be infringing that particular circumstance under normal cases but again the folks are supplying them with the tools for that may come under one of these statutes either inducing it or supplying a component that is what would be referred to in the contributory infringement law as a nonstaple article, something that is almost more purposefully directed at this type of infringement that would be captured as well.

And you can well imagine that in many circumstances it's the vicarious infringer that matters more to the patentee under those cases. You don't necessarily want to sue customers. You don't necessarily want to sue the people who are going through and providing these services but you do want to certainly look not just at the fact that they have the deeper pocket but also where the activities again are more purposefully directed to that type of infringement.

Now, the other infringement category is now becoming almost as broad as the other types of infringement. One that many of you are probably very well aware of is what I have briefly laid out here at the ANDA filing.

And for those that are not focused in on this topic it refers to the submission of documents, applications, materials and methods for regulatory

approval processes. The ANDA refers to an abbreviated new drug application. It refers to a filing before the Food and Drug Administration.

It is possible in a circumstance where you are a generic pharmaceutical manufacturer to forego having to conduct and report an altogether new series of tests for safety and efficacy and other considerations with pharmaceuticals but instead essentially piggyback your application on work that had been done with a brand name patented pharmaceutical.

And you can do this by going to the FDA and claiming that there is the same level of bioefficiency, bioavailability, bioequivalency is another term that they'll use, with what has already been approved by the FDA.

Now, recognize as we go forward that bioequivalency does not necessarily speak to a patent right or how it works vis-a-vis a patent right. It is certainly possible to have a bioequivalent pharmaceutical as a generic that does not infringe the patent claims to patented drug itself because of the way that the formulation is designed or other things that are more specific to each case.

But in any event, you can proceed to the FDA. You can file your abbreviated new drug application and

during that period of time in response to what is known as an Orange Book listing, essentially not particularly creative in name, it has an orange cover, patent holders for brand name pharmaceuticals place patents and their listing and designation into this Orange Book.

By virtue of its listing in the book a generic pharmaceutical manufacturer must elicit a series of certifications upon filing the ANDA. They must say either I'm not going to manufacture this during the term of the patent that's listed or for whatever reason I'm not going to infringe or the patent is invalid or otherwise unenforceable. Those are two of the possible certifications that you can make when you're filing the ANDA.

In response to one of those certifications referred to as Paragraph 4 certification when you're filing, the brand name patent holder may sue the generic pharmaceutical manufacturer. And indeed in virtually all cases -- I'm not even sure I'm aware of any cases where it hasn't -- it does for reasons related to exclusivity periods that are granted to a generic pharmaceutical manufacturer that -- I'm sorry, to a brand name drug manufacturer that ultimately brings that suit.

So that is one type of infringement. In a sense a statutory, declaratory judgment because again, the

generic is not out there marketing. They're still at the first steps of their approval process but by virtue of having filed the ANDA the brand name is now vested with jurisdiction to come in and sue the generic to try to have their rights resolved in advance of that time period.

The flip side of that it's not all great news for the brand name drug manufacturer. The generics will certainly have defenses accorded to it that we'll discuss in detail as we go along as well for their activity during this experimental approval process.

The other aspect of infringement, what I had termed here as the export of unassembled components, deals with circumstances where you are not truly practicing the patent claim because again if the claim is to a combination of A, B and C, I may be able to say well, I have A over here, B here and C oh, somewhere behind me. Don't you worry; I'm not infringing the claim.

And, in fact, you wouldn't be literally infringing that claim because the claim is to the physical combination of those three elements. However, if you are engaged in stockpiling each of those elements in the hopes of exporting this for assembly outside of the territorial bounds of the Patent Act, the Patent Act

has a little news for you. You would be infringing under that particular subsection of 271 for those types of activities.

Now, the flip side of that perhaps is offshore infringement. What happens if I have a patented process here in the United States? Perhaps I don't have coverage to a physical product that's a result of that process, either because of an expiration of the patent or for some other reason it simply was not sought. But I have a process. The process is of putting A, B and C together.

Some may think they can go offshore, again, outside of the territorial reach of the U.S. and assemble A, B and C and now import that into the United States.

Again, because there is not a patent claim to the combination of A, B and C, there is no infringement of that nonexistent patent and there also would be no infringement of the process of putting those together because that was done elsewhere.

Not so fast. Again, we have another statutory subsection that attends to that particular type of activity and says if the product that is imported would otherwise be made by an infringing process or an infringement of the process here in the United States but was simply done offshore, that would be captured under that subsection also.

One of the more recent issues that has come about as well and this I have listed -- although I have listed it in the infringement section actually speaks a little bit more to the damages phase of it, but certainly is something known as pre-grant infringement.

Until recently, as Professor Thomas had mentioned and Dr. Chambers had talked about, patent applications that were filed with the Patent Office were kept confidential.

Now, as a matter of moving closer towards global harmonization of patent laws, certainly other countries have long published patent applications roughly 18 months after the patent application had been filed.

We have now moved closer to that circumstance and in those cases where a U.S. patent applicant is filed not just in the U.S. but in a foreign country as well, their patent application here in the U.S. will be published at about the 18-month time period.

Well, that disclosure has now come coincident with some rights that have accrued to that, in some ways provisional rights of sorts. Essentially if that patent application ultimately gets issued as a patent and an infringer or accused infringer is sued and ultimately held to have infringed, to the extent that they had notice at the time of the disclosure of that patent

application, and more importantly, to the extent that the claims of that application were substantially similar if not identical to the claims of the ultimately issued patent, there can be some damages that have accrued during the period of time before the patent had actually arisen.

Now, the limitation on those damages we will get to is within a reasonable royalty sense. They're not lost profits or other types of actual damages in that nature.

But certainly it is expanding, again, the scope of protection to patent holders in this regard by virtue of having that additional capacity. It used to be no damages ever, no infringement ever until a patent grant had actually been made.

MR. COHEN: Is the disclosure viewed as giving constructive notice?

DR. SUNG: You will actually have to provide actual notice.

MR. COHEN: Actual notice.

DR. SUNG: To the competitors in the area, the prospective infringers. If we are looking at what the standards are ultimately or what the tests are for infringement having looked at the various types of conducts that may result in infringement, this is all

under a preponderance of the evidence standard. Again, nothing more claimed in terms of how we look at this.

Now, there are two types of infringement that we'll be discussing. One is literal infringement and the other is what you may have heard more in the press, the infringement under the doctrine of equivalents.

The concept of literal infringement is a little bit less controversial. Clearly, if there is a patent claim of which somebody is deserving it is both presumed valid as well as adjudged valid in that sense and we're pretty comfortable by saying if it says A, B and C and that's what you do, you're a literal infringer.

What we're a little bit less comfortable with is for a circumstance where you're not really doing A, B and C. You may be doing A, B and -- let's keep it closer -- C prime.

The C varies somewhat. So we're questioning should the patent holder with a claim to A, B and C be allowed to encompass within the scope of their legal right A, B and C prime. And we'll talk about that as well.

Now, some of the methodologies that are involved and here's where all the details come out and the devil is somewhere in them. Claim interpretation is something that has been over the past five years or so revitalized

in terms of the scrutiny that both the Federal Circuit has provided to it as well as the district courts as a result.

The patent claim is the scope of the legal right, not the title, not the abstract, not anything else on that front cover page that Scott showed you.

Unfortunately not everybody understands that. A lot of times you'll pick up a newspaper and it will say, oh, my God, a patent issued to the Internet. Not a good thing. I thought we had the Internet already. I thought somebody else had invented the Internet, until you get to the claims.

And then you look at it and you say, oh, no, it's not really the Internet. It's to this particular application on it. And more specifically it's to the subset of these applications of that.

So again, the title and the abstract aren't really involved with the legal right that is vested with the grant. But when we focus on the claims then we need to ask ourselves not just what the meaning of the words are but what the legal scope as a result of those meanings we ascribe to those words really stand for.

Only then can we compare what the accused device or process is to that properly construed claim. Once we can make that determination, and that has to be done by

the court. The court is within its exclusive province to do it. It may not be submitted to the jury and have the ultimate determination rested as a matter of fact. It is a pure question of law in that determination.

How do we do claim interpretation? Very briefly, the Federal Circuit in particular has championed this cause of public notice, saying that first and foremost the patent claim serves a public notice function.

It defines where the property supposedly starts and ends. And because of that much of the burden of the patent claim interpretation rests with what the patent applicant had done his or herself during the process of the application.

Not only are we going to look at the patent claims and look at how they may be similar, how they may differentiate from one another. We may look to the rest of the patent, the figures, the disclosure but we also look to what's now a public record once the patent issues which is the prosecution history, the correspondence, the exchange, what went on between the Patent Office and the applicant in this fashion.

And very simply stated what you say can and will be used against you in that regard. And that's the essence of prosecution history estoppel which we'll touch on as well.

As I mentioned literal infringement, not really controversial in nature. The test, each and every limitation must be met. Again, if the claim is to A, B and C you must have each of those elements or limitations in the accused product or process.

Just missing one of them, missing one of them even slightly if I now have A, B and C prime, at the very least I can say I don't literally infringe. But we still leave open the prospect of infringement under the doctrine of equivalents.

Without going into the history of it, which would certainly take far more time, and it is past 12:00, the aspect of infringement as a test under the doctrine of equivalents deals with asking a broad question of substantiality or the flip side insubstantiality of differences with regard to a particular element.

So using the hypothetical that I proposed where the patent claim is to A, B and C if I am an alleged infringer practicing A, B and C prime, the court is going to focus on the comparison between the C and the C prime to ask ourselves does the prime make it a substantial change or is it really a trivial insubstantial change?

It doesn't view it as a whole. We don't look at A, B and C together and then compare it to A, B and C prime. We look at the specific element and ask ourselves

is that a substantial or an insubstantial difference?

And the reason what I have just described matters quite a bit as you can well imagine a circumstance where something has 100 elements in its patent claim. And the accused product has 100 elements in its makeup.

It can differ by just one out of those hundred. Ninety-nine of the elements or limitations may be identical in nature but the court is still going to only focus on that one particular element to decide is that change in that element substantial or insubstantial.

And if the determination is that it is a substantial change, the fact that on a quantitative level 99 percent of these particular accused products are exactly like the patent claim, that's going to allow it to escape infringement under the doctrine of equivalents. So that's something to watch out for as well.

MS. MICHEL: Lawrence, it does sometime seem as though courts will talk about comparing the entire accused infringing device to the entire claim. The infringing device works just the same way as the patented invention. Is that improper or is it all right if it's done in addition to the element-by-element test?

DR. SUNG: Well, I think you have hit on it. The element-by -element test still requires you to focus in a comparison of an element in the claim versus an element

in the accused product or process.

But in addition to insubstantiality one way of assessing whether something is substantial or insubstantial is to rely on a historic test known as the Function Way Result test, to ask does this particular element or limitation in the accused process work in substantially the same way and substantially the same function to achieve the same result. And that's one mechanism for determining substantiality or insubstantiality.

The reason that the courts more recently have moved to a broader concept of insubstantial change is because in certain industries the concept of analyzing this under a Function Way Result test were arguably limited.

An example would be in the pharmaceutical area. Perhaps we don't quite know the mechanism of action so assessing it in a Function Way Result tripartite analysis may not give us a very easy resolution. But if we step back and look at the substantiality of it, perhaps in that circumstance it would work a little bit better.

MR. COHEN: Could you tell us is there any relationship between the type of inquiry you're making to determine if you have infringement and the type of inquiry you make in determining if advance is obvious.

DR. SUNG: The answer is yes. Actually, it's a good segue to where we're going here. When we talk about limitations on the application of the doctrine of equivalents there are some very real ones.

Prior art would be the first one in which the doctrine of equivalents should not allow a patentee to go beyond the literal scope of their patent claim and try to encompass an activity or something, product or process, that is in the prior art.

And more importantly not just specifically in the prior art in all-or-none fashion but those obvious variance of the prior art as was discussed earlier. And I like the terminology in terms of the patent-free zone.

Looking at this ability for us to say it's not just the prior art that counts but those things that would have been obvious in practice from that prior art should also not be permissibly recaptured out of the public domain.

So that's one limitation on the application of the doctrine of equivalents. Another one which many of you have probably seen more recently is prosecution history estoppel.

Several years ago the Supreme Court in Warner Jenkinson established that there is a presumption and this goes back to the estoppel by silence. As Dr.

Chambers mentioned there are many times during the course of obtaining a patent that there is an exchange between the examiner and the applicant in which the original claim language that was provided may have been amended.

And we can argue that the amendment may have increased the scope or decreased the scope of the legal right as a result of that amendment but what's important to take away with respect to the doctrine of equivalents in prosecution history estoppel is that when an amendment is made it really for practical effects these days is a burden on the applicant to clarify why the amendment was made.

Now, there are certain rationales, for instance, overcoming the prior art. It really doesn't matter what the definition is, they were disclaiming subject matter because they had to disclaim subject matter.

But we may get into a grayer area where there are circumstances in which amendments were made but it's a little bit less clear why they were made. Well, if there is no explanation contemporaneously in the prosecution history, in the record as to the reasons for these types of amendments we may presume that they disclaim subject matter if later on during litigation we see that this resulted in a narrowing of the scope.

The application of prosecution history estoppel,

as you may know as well, is the subject matter of the Festo case that was argued before the Supreme Court on January 8th. The question is how far does prosecution history estoppel reach here as a limitation to the doctrine of equivalents?

And some people may be saying well, doctrine of equivalents is dead because prosecution history rules. Well, when we look at that we may be able to say there are certain circumstances where it's clear why an amendment was made and that resulted in a disclaimer of subject matter.

However, there may be also circumstances where it's really only in hindsight during litigation that we can establish, again because the courts are the ultimate arbiter, that subject matter indeed was disclaimed.

Maybe the patent applicant wasn't really thinking that they were disclaiming any subject matter but now years later in litigation we're saying, yes, you did. Why didn't you explain yourself? Well, I didn't think there was a problem.

So there is a retroactivity issue that goes along with this as well and that in a very small over-simplified, forgive me, nutshell is the Festo case. The question of what the reach of prosecution history estoppel is and its impact on your ability to apply the

doctrine of equivalents when an amendment has been made in that fashion.

MS. MICHEL: Let me ask just a follow up on doctrine of equivalents. Now, the question of insubstantiality of the differences is a question of fact. And that's going to go to the jury, whereas the limits on application of the doctrine of equivalents I believe they're both questions of law. Is that right?

DR. SUNG: That's right.

MS. MICHEL: And I just want to bring out that point in that I think it provides something of a context for some of the drive behind the recent developments in case law is that at least when I'm wearing my litigator's hat the idea of taking a question of C versus C prime insubstantial to the jury I feel like I have a hard time making that prediction of how that question is going to turn out.

DR. SUNG: Yeah. The procedural advantage of having these be designated as questions of law is apparent. You can look at this; you can litigate this for purposes of dispositive motions and perhaps have interlocutory appeals to the Federal Circuit to help resolve some of these questions based on those dispositive motions.

The matter is that it also vests the Federal

Circuit with a very important role and that it need not defer as a result of those being questions of law and its de novo review. It need not defer to the trial judge in making some of these types of determinations.

But certainly from the litigator's standpoint, keeping some of these perhaps very difficult technical questions about insubstantiality from the fact finder may be good guidance to be able to say even before we engage in questions of technicality and insubstantiality to be able to use some broader legal frameworks to say whether or not the doctrine of equivalents can even make that reach or not.

Okay. Noninfringement as a defense. I didn't do it; not me. Implied license. Certainly everything I have done I admit to but it was all done under authority. Whether or not it's expressed or in this circumstance an implied license. Given our time I'm going to ask if I could just go through some of these defenses with you and I'll certainly be happy to speak with you individually afterwards about this. But I'll try and touch on this in the brief time we have left to go through.

In addition to the authority issue with regard to implied licensing there's a first sale doctrine that essentially, like the copyright circumstance, if I were to sell you a patented product the amount of money I am

charging for that is presumed to have taken into account that compensation which you believe should have vested in your patented right as well.

So if I now take that particular article and go and do something else with it having already purchased that right through you I don't have to pay another license fee or another royalty on top of that.

This comes up into a doctrine known as repair and reconstruction. To what extent may I take something that I have validly purchased and therefore have obtained the right of authority under the patent rights and start tinkering with it?

At what point in time does the amount of repair work that I do on it really recreate a new machine for which the patent holder should have obtained yet another return on their investment in that right? And that is something that the courts wrestle with quite a bit in terms of looking a single use type of limitations that are placed in certain aspects, particularly medical products. We might say single use has safety concerns beyond simply a first sale type of issue.

Experimental use. I want to caution people because the term is used in a variety of different contexts. There is no such thing as an experimental use exception broadly to infringement so in those days when I

was in graduate school and I said well, who would come after me. I have no money. I have really nothing to do with this, and besides, I'm not making any money out of this. Let me just go ahead and take what I have seen in terms of this patent and do it.

Well, it may be true for practical purposes that it just wouldn't be nice to come after me for whatever reason, because I have no money and whatnot, but at the same time, there is no exception to the fact that what I have now done is an infringement.

There is no experimental use exception in that sense. Where it does come into play for purposes of noninfringement is to say, and this is the flip side of our ANDA litigation filing, that where you are doing these activities in furtherance and substantially related to filing for approval, regulatory approval, with an agency, the FDA is an example, the type of work that you are doing would be exempt under 271 from infringement.

And again, that is sort of the other side of the coin which would allow the ANDA filing itself under Paragraph 4 to be the basis for a lawsuit.

MS. MICHEL: There is a Supreme Court case, right, that 19th century case if I'm doing something purely for philosophical inquiry with no commercial motivation whatsoever that there is this exception. Do

you just think that's dead in the water at this point?

DR. SUNG: I think it's potentially anachronistic. But aside from that I think that even if we were to apply that in a common day setting I think that the proof would be extremely difficult to show that what you were doing was purely philosophical in that sense or is purely for a noncommercial motive. The pecuniary interest is quite evolved in that way.

The other thing that was touched on earlier is the first inventor defense. And this principally arises out of the business method context. Congress having been the recipient of a lot of criticism with respect to the State Street decision and opening up business methods as patentable subject matter certainly rushed very quickly to respond to that by enacting Section 273 which provides a defense, particularly for business method patents.

This in some ways is a defense that will be in my estimation transitory in nature. And the reason I say that is not because we will repeal it or anything necessarily like that but the factual circumstances in which such a defense would arise are perhaps decreasing every day.

The reason that the defense came about is until State Street most folks that were interested in protecting an innovation in the business method context

would know not to file a patent application. There was clearly a proscription against that. So, in fact, what they would do is they would retain it as a trade secret or harbor it in some other fashion.

As a result of either keeping it secret or keeping it closer to the vest, the public may not have had the benefit to know that you, in fact, were doing this or that anyone had been doing this.

So when the first business method patent applications were filed, the Patent Office was without an arsenal to respond. Basically, it relies on what's in the public domain, what's in the prior art and here they may not have had anything in the prior art despite the fact that of course people were doing this.

So the business method defense under 273 was enacted to allow evidence of that type of use to come in to defeat the assertion of infringement under a business method patent claim.

First inventor defenses are rather limited in terms of their applicability and their use. And again, I'll be happy to speak with anyone about that further.

Governmental immunity again is tied less as an exception to noninfringement but is pushed over in another form in the 1498 actions that I mentioned earlier. There's another venue rather than the district

courts for an action against the government for patent infringement and that is before the Court of Federal Claims.

The reverse doctrine of equivalents. I must say that when I was asked to put in a few words about the reverse doctrine of equivalents I would not have otherwise thought of this as a big particular issue as a noninfringement defense and was lucky enough to wake up this morning and realize that yesterday there was a Federal Circuit decision issued on this very point which essentially puts the last nail in the coffin in my estimation about the reverse doctrine of equivalents.

And if I can just borrow from this, the Supreme Court referred to the reverse doctrine of equivalents in Graver Tank, a 1950 Supreme Court case. And it says it applies where a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way even though it falls within the literal words of the claim.

An example of this perhaps would be where there are certain proteins that are made through a biological process that have been patented but at the same time what you are now doing is building from the ground up. You're going in with molecular biology and genetic engineering and you're recreating something from scratch. You're not

using the natural biological process.

However, the earlier patent claim would read on your product because ultimately you were trying to achieve the same thing through a different process.

Would that be a possible application of the reverse doctrine of equivalents? It may sound like a good thing but the court goes on here and says, not once has the court, the Federal Circuit, affirmed a decision finding noninfringement based on the reverse doctrine of equivalents. A very powerful statistic and with good reason.

So I think that gives me an indication this is not a good argument to lead off with in your brief because when Congress enacted Section 112 after the decision in Graver Tank it imposed certain requirements that Dr. Chambers talked about in terms of written descriptions and so forth that take into consideration the public policy that was originally at issue when the reverse doctrine of equivalents was constructed. So I think it is anachronistic in that sense and it's very unlikely to prevail in terms of litigation.

Even more quickly, invalidity. Tried under a clear and convincing evidence standard because, as has been explained earlier, patents that do issue issue with a presumption of validity under Section 282.

Because of this there is this concern that they have an in terrorem effect, that once they're out there even if they were invalidly issued we have to go ahead and wait until the patient is dead and the autopsy is performed to figure out that that is the case. So this may not be particularly satisfying in terms of a process for people looking at a patented landscape.

The bases for invalidity are the conditions for patentability which have already been set forth for you. Those same conditions are looked at from an enforcement standpoint to see whether or not the patent, even after having been issued, complies with those. The disclosure requirements under Section 112 as well.

The reason I also include inventorship here is in more recent days -- well, let me back up just a bit. I would say that traditionally patent litigation in terms of its history had looked for invalidating patents by looking at what was in the prior art or whether or not the disclosure in the patent had been sufficient. And those were the primary grounds of invalidating patents.

These days we're seeing more and more examples of circumstances where defendants are questioning the inventorship and the correct designation of who is an inventor on a particular patent as a basis for invalidity.

If there is an omission or an incorrect inventor designated on a patent, that is the basis for an invalidity argument. Now, of course, it can be corrected if the omission or the defect resulted from good faith, more importantly, not bad faith.

So under those situations maybe the remedy could be a correction of inventorship. However, if there were bad faith that were discovered in the process, the patent could be invalid on that basis.

Now, why is this so important in the patent realm? Because typically invention is not a sole process. It can be very collaborative in nature. And the question of that collaboration and where we test it may lead us to people who are not otherwise listed as inventors or on the flip side were listed as inventors although they don't meet the legal definition of an inventor.

The matter of who is an inventor is a question of law. It is not something that we can simply ascribe and say well, they gave me all the reagents and therefore I've always liked John, and John should be on the patent. It isn't a matter of attribution.

So because of that that is another avenue for these types of invalidity challenges more recently. As you can well imagine it is extremely cost effective for

an accused defendant to go find somebody who may validly be a co-inventor and say, would you like to take pennies on the dollar for what I'm actually being sued for and license me your rights as a co-inventor to the patent?

And, in fact, we have had examples of that in litigation that have been successfully done. And of course the new co-inventor says of course I would be willing to take this amount of money. No one has ever thought of me as the co-inventor of this patent.

By virtue of being a co-inventor you also have rights in the entirety to the patent as a result and therefore a situation like what I have just described can come about.

Unenforceability is another arm of disarming patents. Instead of looking at an invalidity circumstance where the patent has ultimately been pulled they are no longer enforceable because of certain types of equitable considerations that go on.

One is inequitable conduct which deals primarily with fraud on the Patent Office. To the extent that an applicant has not met her duty of candor which as has been talked about before every patent applicant is required to disclose that of which they know which may be material to the patent examiner for examination.

If they have hidden something or they have

omitted something or they have buried something in the file, all these things may give rise to a finding of inequitable conduct from which unenforceability may be the result.

Laches and estoppel, patent misuse and, hey, antitrust can all be grounds for this as well. Overreaching ties a little bit into the patent misuse area and the varying standards of that deal more with contractual obligations in circumstances where as private party transactions you are saying essentially don't challenge what I am about to sell.

What's the difference inherently between the unenforceability aspect and invalidity? Although for a particular defendant they may be quite similar in practical effect invalidity is done according to patent claims. So, for example, if I have claims one through ten I would need to prove by clear and convincing evidence invalidity of claims one through ten individually.

On an unenforceability matter the inequitable conduct, for example, would taint the entire prosecution of that patent application and as a result the entire patent would be unenforceable. So it is perhaps getting to almost the same result certainly through two different mechanisms but for two different reasons as well.

Lastly, remedies. When we are looking at the various remedies that are available similar to other areas of the law certainly injunctive relief in preliminary injunctions as well as permanent injunctions damages may be accorded in terms of actual damages through lost profits calculations but also something known as a reasonable royalty.

There is a floor to patent relief in a monetary fashion that is determining what in the hypothetical the willing licensee would have paid a willing licensor for the use of those patent rights prior to the infringement known as a hypothetical negotiation between the parties to establish what a reasonable royalty would have been for the infringement.

Evidence that can be looked towards, other types of licenses, other means of valuation, all I can say is with regard to patent valuation it is a difficult area, a with a lot of arguable aspects to it so that this is not an easy determination to be made. However, there is quite a bit of case law which provides some good guidance.

Enhancement of damages, also quite important. Beyond the compensatory damages that are available for finding of willful infringement you may be subject to treble damages as well as costs and attorneys' fees by

statute.

Willful infringement usually requires notice certainly and the ability to flagrantly disregard the patentee's rights.

A mechanism by which that typically occurs is that if I'm put on notice of a particular patent on my own accord I decide I'm not within the scope of the patent. It's okay. I'll just continue what I'm doing. It was really my obligation to obtain competent independent legal opinion regarding what the scope of the patent was and what my operation was.

In the absence of that, typically the courts will look at and be rather strict about whether you were a willful infringer. But in the presence of a competent independent legal opinion even if it's incorrect as a matter of litigation, that will usually help rebut successfully an issue of you being a willful infringer and avoid that type of enhancement of damages. And with that, thank you very much for your time.

MS. MICHEL: Could I ask either of you to say a couple of words on Symbol v. Lemelson as a defense? And not in the commentary sense but simply the significance or the basic holding.

DR. SUNG: One of the defenses that I had listed on there for infringement was laches and estoppel. This

is a little bit of a cousin to that which is something known as prosecution laches which deals with circumstances, in this particular case, Lemelson is the patentee of a certain technology for which the applications were originally filed in the 1950s.

But being able to use the patent system to his advantage he was able to continue applications before the Patent Office and have them be issued at a time where his technology, which was to bar-code scanning, was more commercially practicable.

As a result of that very commercial success in terms of his patent rights and the licensing, they have been challenged in terms of the patents under the basis of prosecution laches, saying, despite the fact that you have complied with the existing statutes and regulations towards prosecution, there can still be a laches argument that is made and that was upheld by the Federal Circuit recently in this case.

So that is, again, a circumstance which I don't know that we've heard the last word on but certainly is available as of today.

MS. MICHEL: Totally different issue, I'd be interested in your thoughts on this hypothetical. I'm a copier repair person; I take a patented spare part and put it in the machine. I never push the copy button.

Have I used the patented invention?

DR. SUNG: Yeah. This is the reason that the term "use," I think, certainly can withstand better definition about what we believe to be within the scope of the Patent Act.

I think that it's arguable to say that it may be a causation matter but it certainly would fit within a very broad definition of the word "use," because you are looking at some type of result that has occurred here whether through your agent personally or through a third party. So I think that's certainly open for interpretation at this point.

MR. COHEN: Okay. I think we have finished. I want to thank all of our panelists for just an outstanding job. and I want to thank all of you for attending.

(Whereupon, the proceeding concluded at 12:50 p.m.)

C E R T I F I C A T I O N O F R E P O R T E R

CASE TITLE: HEARINGS ON COMPETITION AND INTELLECTUAL PROPERTY LAW AND POLICY IN THE KNOWLEDGE-BASED ECONOMY

HEARING DATE: FEBRUARY 8, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: February 15, 2002

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DEBORAH M. TURNER

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

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SARA J. VANCE